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Data Entry Training for
Oracle Clinical - Remote Data Capture
(OC-RDC)
Version 4.5 CLASSIC

Classroom
Learner Guide

3rd Edition, September 27 , 2005

This manual is the third edition of the Learner Guide. It supersedes all previously issued editions of OC-RDC Version 4.5 Classic.

Table of Contents

Introduction to OC-RDC

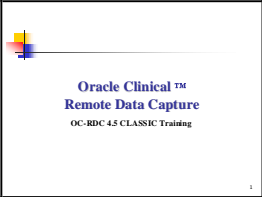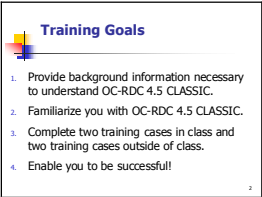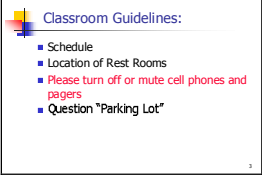|	
Introduction	This lesson provides an overview of the Oracle Clinical Remote Data Capture system.
Lesson Objectives	After completing this lesson, learners will be able to: 1. State the minimum system requirements for using Oracle Clinical (OC) Remote Data Capture (RDC). 2. List the data management functions that can be performed in OC-RDC. 3. Define common terms used in OC-RDC.
Background	Oracle® Clinical (OC) is a commercially available clinical trials data management system developed by Oracle Corporation. OC is used by numerous pharmaceutical and biotechnology companies, contract research organizations, and other medical and academic institutions. OC allows for data entry at a central location into a central database, and it also allows for web-based data entry from many locations into a central database. The web-based data entry application is called Remote Data Capture (RDC). RDC is fully integrated with the OC data management system. It allows clinical sites to enter and correct data through interactive web-based sessions. There is no special hardware required for a clinical site to access and use OC-RDC. It is necessary, however, to have a personal computer that meets ordinary standards for use with today's software and to download a set of free software components. In addition, it is necessary to have an Internet Service Provider (ISP). While it is possible to use OC-RDC with a regular dial-up modem that has a baud rate of at least 56kbps, it is preferable to have a faster connection through a DSL line, a cable modem, or other high-speed connection at your institution.

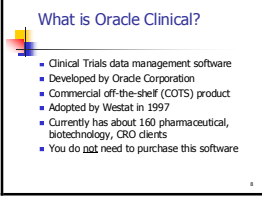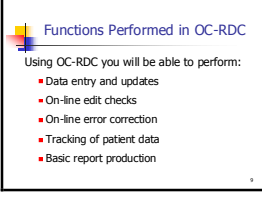|	
Background (cont.)	Through OC-RDC, clinical sites will be able to perform the following data management functions: • Data entry and update; • On-line edit checking; • On-line error correction; • Tracking of patient data; and • Running basic reports. This training course covers the basic functions that a clinical site will need to perform in OC-RDC Version 4.5 CLASSIC. Instructions in this guide might not be applicable to earlier or later versions of OC-RDC. If you are using a different version of OC-RDC, please contact your Westat study representative to determine if there are other instructions available, or call the Westat RDC Help Desk. This Participant Guide is a product of Westat and was developed strictly for authorized Westat OC-RDC users. Oracle Corporation has not approved this guide. Use of this guide is prohibited except as authorized by Westat.
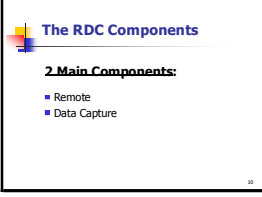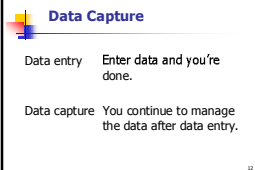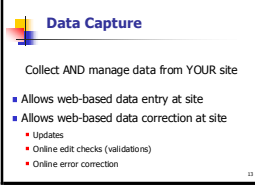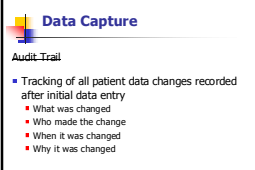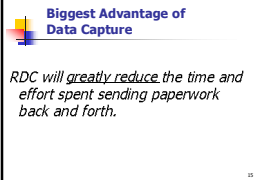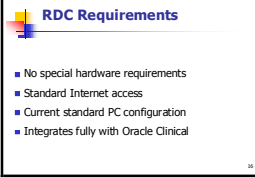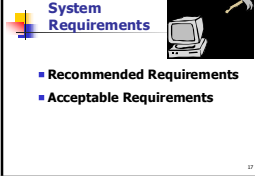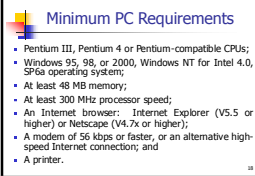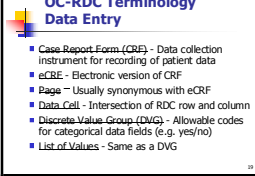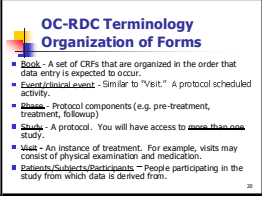
Screen Visual		Notes
Oracle Clinical ™ **Remote Data Capture** OC-RDC 4.5 CLASSIC Training	Welcome to this Oracle Clinical – Remote Data Capture (OC-RDC) training session!	
Training Goals 1. Provide background information necessary to understand OC-RDC 4.5 CLASSIC. 2. Familiarize you with OC-RDC 4.5 CLASSIC. 3. Complete two training cases in class and two training cases outside of class. 4. Enable you to be successful!	Course Training Goals 1. Provide background information necessary to understand the OC-RDC 4.5 CLASSIC application. 2. Familiarize you with OC-RDC 4.5 CLASSIC. 3. Complete two training cases in class. 4. Complete two training cases outside of class. 5. Enable you to be successful	
Classroom Guidelines: ■ Schedule ■ Location of Rest Rooms ■ Please turn off or mute cell phones and pagers ■ Question "Parking Lot"	Classroom Guidelines: • Schedule • Location of Rest Rooms • Other Facilities • Please turn off or mute cell phones and pagers • Question "Parking Lot" (off-line and follow-up questions to be handled outside of class.)	

Today's Lesson Plan 1. Introduction to OC-RDC 4.5 CLASSIC 2. Logging on to the Training Database 3. The OC-RDC Main Window (The Spreadsheet) 4. Searching the study database 5. Data Entry 6. Adding a page 7. Adding a visit 8. Validating and Correcting Discrepancies 9. Printing Reports & CRFs	Course Schedule – Nine Lessons 1. Introduction to OC-RDC 4.5 CLASSIC 2. Logging on to the Training Database 3. The OC-RDC Main Window (The Spreadsheet) 4. Searching the study database 5. Data Entry 6. Adding a page 7. Adding a visit 8. Validating and Correcting Discrepancies 9. Printing Reports & CRFs	
Introduction to Oracle Clinical – Remote Data Capture **OC-RDC 4.5 CLASSIC**	Introduction to Oracle Clinical – Remote Data Capture (OC-RDC) 4.5 CLASSIC	
Introduction–Training Objectives After completing this lesson, students will be able to: 1. Explain OC-RDC purpose and capabilities 2. Recognize the minimum system requirements for using OC-RDC 3. List the data management functions that can be performed in OC-RDC 4. Define common terms used in OC-RDC	After completing this lesson, you will be able to: 1. Explain OC-RDC purpose and capabilities; 2. Recognize the minimum system requirements for using OC-RDC; 3. List the data management functions that can be performed in OC-RDC; and 4. Define common terms used in OC-RDC.	
Overview Remote Data Capture (RDC) is a user-friendly mechanism that ~~gives sites greater control~~ over the process of ~~entering, correcting,~~ and ~~managing~~ their data.	Oracle® Clinical (OC) is a commercially available clinical trials data management system developed by Oracle Corporation. OC is used by numerous pharmaceutical and biotechnology companies, contract research organizations, and other medical and academic institutions. OC allows for data entry at a central location into a central database, and it also allows for web-based data entry from many locations into a central database. The web-based data entry application is called Remote Data Capture (RDC). RDC is fully integrated with the OC data management system. It allows clinical sites to enter and correct data through interactive web-based	

	sessions.	
What is Oracle Clinical? ■ Clinical Trials data management software ■ Developed by Oracle Corporation ■ Commercial off-the-shelf (COTS) product ■ Adopted by Westat in 1997 ■ Currently has about 160 pharmaceutical, biotechnology, CRO clients ■ You do <u>not</u> need to purchase this software	Oracle Clinical is a Commercial off-the-shelf (COTS) product. This means that it is not a proprietary, custom-developed system. Use of Oracle Clinical to manage clinical trials at Westat began in 1997. Oracle Clinical is currently used by over 160 pharmaceutical, biotechnology, and CRO companies. You do <u>NOT</u> need to purchase the Oracle Clinical software in order to use OC-RDC to record and track study subject data.	
Functions Performed in OC-RDC Using OC-RDC you will be able to perform: ■ Data entry and updates ■ On-line edit checks ■ On-line error correction ■ Tracking of patient data ■ Basic report production	Through OC-RDC, clinical sites will be able to perform the following data management functions: - Data entry and updates - On-line edit checks - On-line error correction - Tracking of patient data - Basic report production	
The RDC Components **2 Main Components:** ■ Remote ■ Data Capture	To better understand how OC-RDC works, we can break down the name of this system into its component parts: - <u>Remote</u> and - <u>Data Capture</u>	

Remote ■ Connect From Your Site to Westat ■ Via the Internet	RDC is a system that allows study staff to input data into a database located at another site. In this case, the database is located at a Westat facility. The data is transferred from study site to the database using the Internet.	
Data Capture Data entry — Enter data and you're done. Data capture — You continue to manage the data after data entry.	RDC is a data management system. That means that it is responsible for both accepting raw data entry, as well as managing the process of validating and correcting that data.	

Data Capture
 	
Collect AND manage data from YOUR site
■ Allows web-based data entry at site
■ Allows web-based data correction at site
  ■ Updates
  ■ Online edit checks (validations)
  ■ Online error correction
	The data management part of the RDC process includes:
	
	• Processing updates to information
	• Online edit checks of the data
	• Online error correction	

Data Capture
 	
Audit Trail
■ Tracking of all patient data changes recorded after initial data entry
  ■ What was changed
  ■ Who made the change
  ■ When it was changed
  ■ Why it was changed
	Part of this data management process is keeping an audit trail on all data changes. OC-RDC tracks:
	• What was changed
	• Who changed it
	• When it was changed
	• Why it was changed	

Biggest Advantage of Data Capture RDC will *greatly reduce* the time and effort spent sending paperwork back and forth.	The biggest advantage of using RDC is that the RDC system will greatly reduce the time, effort, and expense of sending paperwork back and forth between study site and the data management location. Paper records are still vitally important. The original documents must be maintained and preserved as before. However, using RDC makes the data available faster and with more reliability, because the data input can be checked for errors immediately.	

RDC Requirements • No special hardware requirements • Standard Internet access • Current standard PC configuration • Integrates fully with Oracle Clinical	The Oracle Clinical-Remote Data Capture system does not require any special hardware on the user's computer. RDC uses standard Internet access to transfer data from the study site to the database. Most current computers are completely compatible with OC-RDC and the data collected using OC-RDC integrates fully with the Oracle Clinical databases.	
System Requirements • **Recommended Requirements** • **Acceptable Requirements**	While Oracle does issue a list of "Recommended Hardware and Software Requirements," the PC requirements for using OC-RDC here at Westat are different.	
Minimum PC Requirements • Pentium III, Pentium 4 or Pentium-compatible CPUs; • Windows 95, 98, or 2000, Windows NT for Intel 4.0, SP6a operating system; • At least 48 MB memory; • At least 300 MHz processor speed; • An Internet browser: Internet Explorer (V5.5 or higher) or Netscape (V4.7x or higher); • A modem of 56 kbps or faster, or an alternative high-speed Internet connection; and • A printer.	Westat OC-RDC minimum PC Requirements include: • Pentium III, IV or other Pentium-compatible CPU; • Windows 95, 98, or 2000, Windows NT for Intel 4.0, SP6a operating system; • At least 48 MB memory; • At least 300 MHz processor speed; • An Internet browser: Internet Explorer (V5.5 or higher) or Netscape (V4.7x or higher); • A modem of 56 kbps or faster, or an alternative high-speed Internet connection; and • A printer.	.
OC-RDC Terminology Data Entry • Case Report Form (CRF) - Data collection instrument for recording of patient data • eCRF - Electronic version of CRF • Page – Usually synonymous with eCRF • Data Cell - Intersection of RDC row and column • Discrete Value Group (DVG) - Allowable codes for categorical data fields (e.g. yes/no) • List of Values - Same as a DVG	Before beginning to use OC-RDC, we must define some commonly used terms and phrases. The terms used in OC-RDC are generally those used by the pharmaceutical industry for clinical trial research, with a few exceptions. The terms that it will be important to understand in order to use OC-RDC effectively are the following:	
	Case Report Form (CRF) - The paper data collection instrument where patient data is recorded.	
	Electronic Case Report Form (eCRF) - An electronic representation of the CRF.	

	Page – In OC-RDC page is usually synonymous with a CRF.	
	Data Cell – In the OC-RDC spreadsheet, the intersection of a row and a column is called a cell. Each cell represents the data collected for a particular patient (the row) for a particular eCRF page (the column).	
	Discrete Value Group (DVG) - The complete list of predetermined values for a data field that uses categories as responses, e.g. "yes, no" or "high, medium, low."	
	List of Values – A Discrete Value Group (DVG.)	
OC-RDC Terminology Organization of Forms ■ Book - A set of CRFs that are organized in the order that data entry is expected to occur. ■ Event/clinical event - Similar to "Visit." A protocol scheduled activity. ■ Phase - Protocol components (e.g. pre-treatment, treatment, followup) ■ Study - A protocol. You will have access to more than one study. ■ Visit - An instance of treatment. For example, visits may consist of physical examination and medication. ■ Patients/Subjects/Participants – People participating in the study from which data is derived from.	**Book** - A sequence of eCRF pages to be collected in a study. A study may include more than one book. The correct book <u>must</u> be chosen in the Selections window before you enter any data.	
	Event/clinical event - A single occurrence of data collection that is planned to occur according to the protocol schedule. (Usually synonymous with a study visit.)	
	Phase – A group of visits, as defined by the study designer, (e.g., pre-treatment, treatment, and follow-up phases).	
	Study – A protocol. You may have access to more than one study.	
	Visit - An instance of treatment. For example, visits may consist of physical examination and medication.	
	Patients/Subjects/Participants – People participating in the study from which data is derived.	

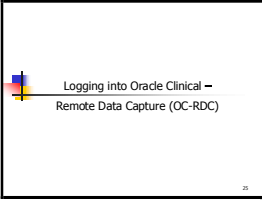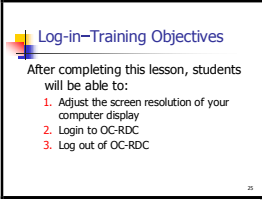|		
OC-RDC Terminology **Data Editing** ■ Validation - An edit check of the data. ■ Univariate validation - Edit check of a single data field. ■ Multivariate validation - Edit check that compares 2 or more data fields. ■ Discrepancy - Inconsistency between an actual and expected value. 16	**Validation** - An edit check of the data.	
	Validate - The process of performing data edit checks.	
	Univariate validation - An edit check of a single data field for allowable value and data type (e.g., date).	
	Multivariate validation - An edit check that compares two or more data fields on a single form or across multiple forms.	
	Discrepancy - An inconsistency between an actual data value and the potential value expected by the study designer.	
OC-RDC Terminology **Data Editing** ■ Univariate discrepancy - A discrepancy that involves a single data value. For example, 98.6 is outside the range of expected values for body temperature measured in degrees Celsius ■ Multivariate discrepancy - A discrepancy caused by more than one data value. For example, a start date being later than an end date; obviously, you expect the start date to be earlier. ■ Audit trail - A list of all changes to the data record after initial entry, including what was changed, who made the change, when it was changed, and why it was changed. 22	**Univariate discrepancy -** A discrepancy that involves a single data value. For example, 98.6 is outside the range of expected values for body temperature measured in degrees Celsius.	
	Multivariate Discrepancy - A discrepancy caused by more than one data value, (e.g.., a start date being later than an end date.) Obviously, you expect the start date to be earlier.	
	Audit trail - A list of all changes to the data record after initial entry, including what was changed, who made the change, when it was changed, and why it was changed.	
OC-RDC Terminology **Data Editing** ■ Verification - Confirmation of the entered data against source documentation. Verification is accomplished form by form. This is a site monitor task in RDC. ■ Approval − Approval of the entered data against source documentation. Approval is accomplished form by form. The approval feature constitutes an electronic signature. This is a Primary Investigator (PI) task in RDC. 23	**Verification -** Confirmation of the entered data against source documentation. Typically performed by site monitors.	

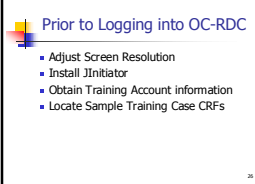|		
	Approval - Approval of the entered data. Approval is accomplished form by form. The approval feature constitutes an electronic signature. This is a Primary Investigator (PI) task in OC-RDC.	
	New features found in RDC version 4.5 include: – Updated Interface – Activity List – Group Activities – Investigator Comments – Blank Flag processing Tool – Patient Data Reports **Updated Interface –** With the introduction of OC-RDC version 4.5 the workspace has been updated to give it a more intuitive look and feel. The RDC Spreadsheet utilizes new CRF icons designed to provide "at-a-glance" feedback on the status of each eCRF. Menus and windows have also been enhanced to make them easier to navigate and easier to use.	
	Activity List – New to RDC version 4.5 is the Activity List. The Activity List is designed as an alternative to the Search window. Both can be used to select a set of patients to display in the RDC workspace. The Activity List window allows the user to select a task, rather than a set of search criteria. Examples of tasks found in the Activity List are "Start data entry for a next patient," and Review open discrepancies." The study sponsor can define as many Activities as needed. Additionally, activities can be restricted or granted based on the study, site or user role. **Note:** The activity list must be enabled by the system administrator. Some studies will not use the activity list feature.	
	Group Activities – Users with appropriate permission levels can now change the verification, approval or lock status of a group of CRFs using the Group Activities menu.	
	Investigators Comments and Approvals– Investigators can now enter, review, and navigate to	

	comments for all datapoints within a CRF. Investigator can also approve CRFs directly within the PDF view.	
	Blank Flag processing Tool – Users can now change the blank flag status of a CRF or a CRF section through a window interface called the Blank Flag Processing Tool.	
	Patient Data Reports – The Patient Data Reports in OC-RDC version 4.5 allow investigators to maintain paper copies of all CRF data that has been entered into the database. Reports can be generated as blank forms, with limited information (such as patient ID #, PI site name, etc.) or with all collected data. The Patient Data Reports provide site personnel with access to hard copy audits, discrepancy, and investigator comment information.	

Summary	Oracle Clinical allows data to be entered at a central location into a central database, and it also allows for web-based data entry from many locations into a central database. The web-based data entry application is called Remote Data Capture (RDC). RDC allows clinical sites to enter and correct data through interactive web-based sessions.
	Through OC-RDC, clinical sites will be able to perform the following data management functions:
	• Data entry and update;
	• On-line edit checking;
	• On-line error correction;
	• Tracking of patient data; and
	• Running basic reports.
Review	1. What is the minimally acceptable Windows operating system for using OC-RDC?
	2. What is the minimally acceptable modem speed for using OC-RDC?
	3. List the data management functions that can be performed in OC-RDC.
	4. Define the following terms:
	• eCRF
	• Univariate Validation
	• Multivariate Discrepancy
	• Discrete Value Group (DVG)
	• Book
	• Data Cell

LOGGING ON TO OC-RDC

Introduction	This lesson describes the procedures for adjusting screen resolution to maximize the OC-RDC display. The lesson also describes how to login to the OC-RDC database.
Lesson Objectives	After completing this lesson, learners will be able to: 1. Adjust the screen resolution of the computer display 2. Login to OC-RDC 3. Log out of OC-RDC
New Terms	The following new term is introduced in this lesson: – **User identification (ID)**—Code that identifies a user to the OC-RDC system
Background	OC-RDC can only be accessed through an Internet connection, and all data entry and data editing must be done while logged into OC-RDC. Before you attempt to use OC-RDC, you must do the following: **Step 1**: Confirm that you have the necessary computer hardware, software, and Internet connection as described in the *Introduction to OC-RDC*. **Step 2**: Obtain an OC-RDC user name and password from your Westat study representative. **Step 3**: Obtain the URL (website address) for the OC-RDC website from your Westat study representative. **Step 4**: Test your access to OC-RDC. Occasionally, firewall problems prevent clinical site users from downloading the file necessary to run OC-RDC. If you encounter a problem gaining access to OC-RDC, call the Westat RDC Help Desk for assistance. You can also contact your local systems administrator to investigate any firewall restrictions at your site.
WARNING!	For study security purposes, please do not tape your OC-RDC password or your OC-RDC bookmark to the computer monitor. ***Security of data is a requirement of 21 CFR Part 11.***

Screen Visual		Notes
Logging into Oracle Clinical – Remote Data Capture (OC-RDC)	Logging into Oracle Clinical – Remote Data Capture (OC-RDC)	
Log-in–Training Objectives After completing this lesson, students will be able to: 1. Adjust the screen resolution of your computer display 2. Login to OC-RDC 3. Log out of OC-RDC	After completing this lesson, learners will be able to: 1. Adjust the screen resolution of your computer display; 2. Login to OC-RDC; and 3. Log out of OC-RDC.	
	This training allows you to become familiar with OC-RDC data entry standards, commands commonly used in the OC-RDC system, and the process of handling data discrepancies. The OC-RDC database being used in this training course uses generic test data and is not specific to your particular project. The contents and validation checks of your project database will be different, but the basic procedure for accessing and using the OC-RDC system will be similar to that of the training database. The data used in this training is for training and testing procedures only. Every effort has been made to provide realistic values. But, in order to create the necessary training scenarios, some unrealistic values are included in the training data.	

Screen Visual		Notes
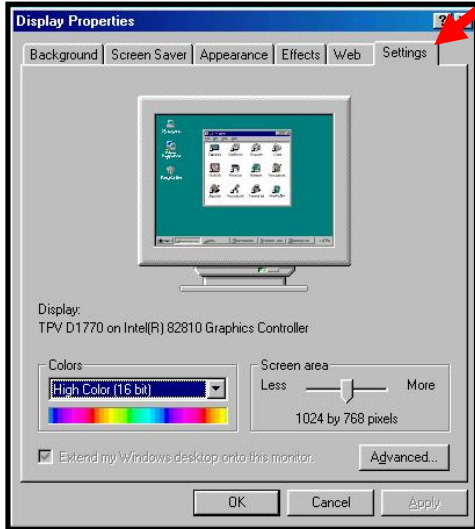
Prior to Logging into OC-RDC
▪ Adjust Screen Resolution
▪ Install JInitiator
▪ Obtain Training Account information
▪ Locate Sample Training Case CRFs
	Training Materials
	
	The following items are needed in order to complete this training:
	  ▪ My OC-RDC Bookmark;
	  ▪ *Participant Manual for OC-RDC Version 4.5CLASSIC*; and
	  ▪ Four Sample Training Cases.
	Contact your Westat study representative if you are missing any of these items.
	
	My OC-RDC Bookmark
	
	The "My OC-RDC Bookmark" contains the information needed to access the training database.
	
	NOTE: after completion of this training, you will be provided with a different website URL, Username, Password and Database name for your project-specific databases.
	
	Participant Manual for OC-RDC Version 4.5 CLASSIC
	
	This manual contains step-by-step procedures and screen images for relevant OC-RDC functions. It will also be a useful reference tool once you begin project-specific OC-RDC tasks.
	
	Training Cases
	
	Training Cases have been designed to assist you in practicing data entry and discrepancy management. Each file represents a completed set of case report forms for your assigned patients (refer to Patient IDs documented on the OC-RDC bookmark.)	

OC-RDC Time Out Function	**Note:** OC-RDC databases employ numerous security features to protect the confidentiality and integrity of study data. One of the security features of OC-RDC is an automatic time-out after several minutes of non-activity. Typically the time out is set to 30 minutes. After 30 minutes of inactivity, a user's access to the study database times out. When this happens, the user must log on to a new OC-RDC session.	
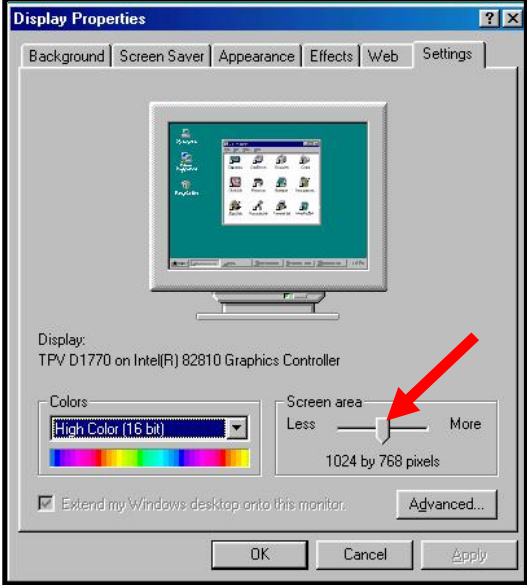
Screen Visual		Notes
	After completing all four training cases, contact your Westat study representative for assignment of your OC-RDC project-specific (Production) database User Name and Password. **Need Help with OC-RDC?** Contact the OC-RDC Help Desk or your Westat study representative.	

Hands-on Exercise: Changing the Screen Resolution

Scenario: Prior to opening OC-RDC and logging on, you want to change your screen resolution to match the system recommendations.

Step	Instructions/Screen Visual	Notes
Background	OC-RDC displays a substantial amount of information on your computer monitor. To allow you to work most effectively, Oracle recommends that you view OC-RDC at a minimum screen resolution of 1024x768 pixels. You can use OC-RDC at a lower resolution, but if you do so, you will need to scroll both vertically and horizontally to see all of the information.	
Adjust the Screen Resolution	To adjust the screen resolution: 1. Click the "Start" button and select ***Settings***, and then ***Control Panel***	
	2. From the Control Panel select ***Display*** to open the Display Properties screen.	
	3. Click on the ***Settings*** tab 	
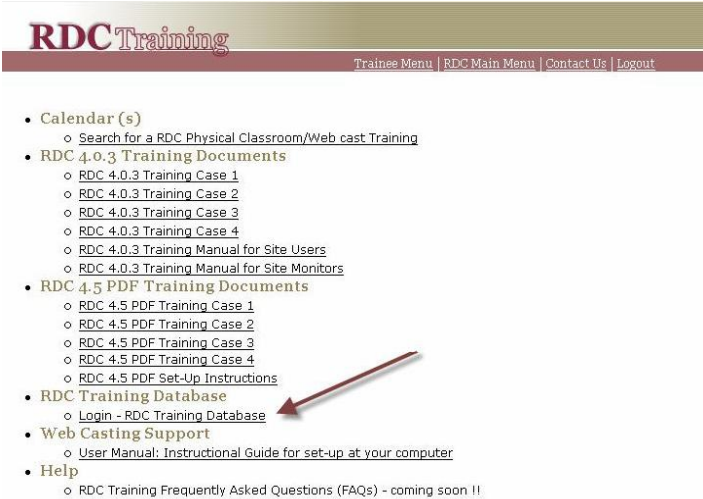
Step	Instructions/Screen Visual	Notes
	4. In the "Screen area" section of the dialog box, click and hold your left mouse button as you move the pointer to 1024x768 pixels. (Windows default setting is either 800 by 600 pixels or 640 by 480 pixels)	
	5. Click **Apply**, and then click **OK**. 6. Depending on your system, you may need to restart your computer for the settings to take effect.	

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Hands-on Exercise: Logging on to OC-RDC

Scenario: You are ready to open OC-RDC and log on.
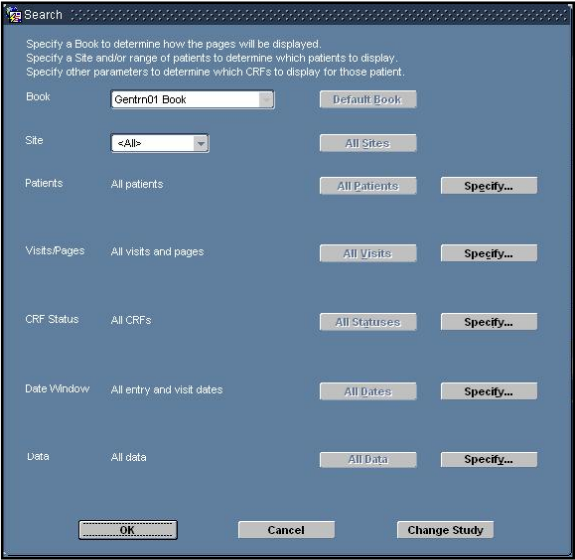
Step	Instructions/Screen Visual	Notes
	Note: This training class uses a special training database. The training database uses generic information and sample cases used only for training. This training program is designed to give you a broad overview of the OC-RDC application. Specifics about the eCRFs used in your study protocol may be covered in subsequent training programs delivered by your project team.	
Launch your web browser	1. Launch your Internet Browser (Internet Explorer or Netscape Navigator) by: a. Double clicking on the desktop icon, -or- b. Selecting the program from the start menu.	
Access the RDC Training Website	This training class requires that you log-on to the RDC Training website before accessing the direct link to the OC-RDC. – Enter the URL for the RDC Training website.	

Step	Instructions/Screen Visual	Notes
	2. At the login screen, a. Enter the required username and password as indicated on your "My OC-RDC Bookmark." b. Click the LOGIN button. **Note**: The username and password required to enter your project website *may* be different from your OC-RDC username and password.	
	3. Click on the link to "Login – RDC Training Database.	

Step	Instructions/Screen Visual	Notes
	4. Click on the pull-down arrow and select: RDC V 4.5 PDF & Classic *RDC Login* RDC 4.5 PDF & Classic LOGIN TO THE TRAINING DATABASE 5. Click on the "LOGIN TO THE TRAINING DATABASE" button	
	2. Wait for the OC-RDC application to load. As it is loading, the box shown below will appear. **Do not** c**lose this window**. If you close this window, you will exit the OC-RDC application. Oracle Pharmaceutical Application… Please do not close this window with a RDC session running. Closing the window will cause report/file viewing and help to stop working.	
Login to the RDC database	1. After the OC-RDC application loads, the "Logon" screen will be displayed. Logon Username: Password: Database: Connect Cancel	
	2. Click in the Username field and enter your OC-RDC Username and press <**Tab**> to advance to the Password field.	

Step	Instructions/Screen Visual	Notes
	3. Enter your OC-RDC Password and press <**Tab**> to advance to the Database field.	
	4. Enter the name of the OC-RDC Database.	
	5. Click the **Connect** button.	
Read the System News	The News dialog box appears. It will contain news of general interest about OC-RDC from Westat. 	
	Click the OK button to close the news dialog box.	If this study does not use the activity list, skip ahead to the start of the search window section on page 12.
Select the Study Using the Activity List	1. If you have access to more than one study, you can change studies by clicking on the Change Study button. 	

Step	Instructions/Screen Visual	Notes
	2. If your study uses the Activity List feature, it will display automatically. The Activity List window uses a task-based system to select patient data to be displayed on the RDC spreadsheet. 	
	3. Click on the Show All Data for PDF 1 link. 	

Step	Instructions/Screen Visual	Notes
Select the Study using the Search Window	If your study does not use the Activity List, the search window will display automatically.	
	Click OK to display all of the patients in the training database.	

Summary	OC-RDC can only be accessed through an Internet connection, and all data entry and data editing must be done while logged on to OC-RDC. Before you attempt to use OC-RDC, you must do the following:
	Step 1: Confirm that you have the necessary computer hardware, software, and Internet connection.
	Step 2: Adjust your screen resolution
	Step 3: Download and Install Adobe Reader and RDC plugins (See Appendix A for detailed download, installation and configuration instructions.)
	Step 4: Obtain an OC-RDC user name and password from your Westat study representative.
	Step 5: Obtain the URL (website address) for the OC-RDC website from your Westat study representative.
	Step 6: Log into OC-RDC
Review	1. What steps are used to adjust the screen resolution of your computer?
	2. In order to log in to the OC-RDC program what three pieces of information are needed?
	3. Can OC-RDC users have access to more than one study at a time?
	4. When is this training course complete?
	5. How will you gain access to the "live" production database?
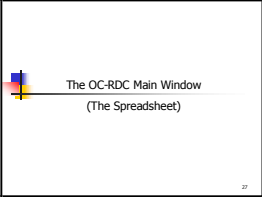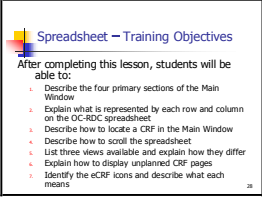
The OC-RDC Main Window (The Spreadsheet)

Introduction	The OC-RDC main window is composed of four main sections: • Menu bar • Toolbar • Spreadsheet • Task Tabs The Menu bar gives you access to all commands in RDC. Menu options are accessible via the mouse or through key combinations. The Toolbar gives you access to frequently used commands and functions. Toolbar options are accessible via the mouse only. The RDC spreadsheet is the main location for working with patients and CRFs. The Task Tabs allow the user to analyze data, handle discrepancies, and approve, verify or track revisions to patient data while working in the Data Entry window or the RDC spreadsheet.
Lesson Objectives	After completing this lesson, learners will be able to: 1. Describe the four primary sections of the OC-RDC Main Window 2. Explain what is represented by each row and column on the OC-RDC spreadsheet 3. Describe how to locate a specific CRF in the OC-RDC Main Window 4. Describe how to scroll the spreadsheet 5. List the three different views available within OC-RDC and explain how they differ 6. Explain how to display unplanned CRF pages 7. Identify the eCRF icons and describe what each means
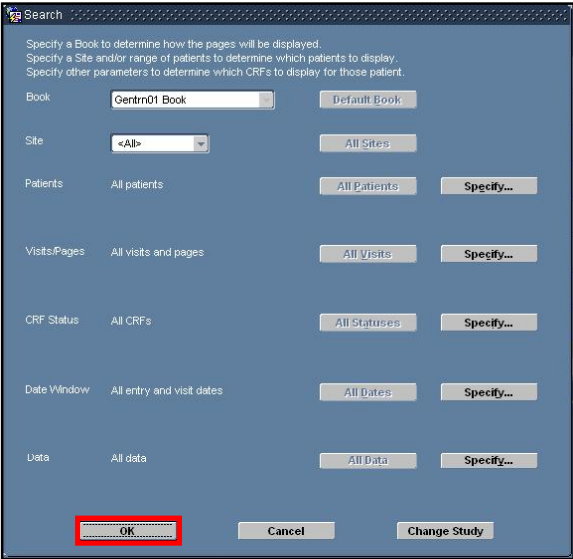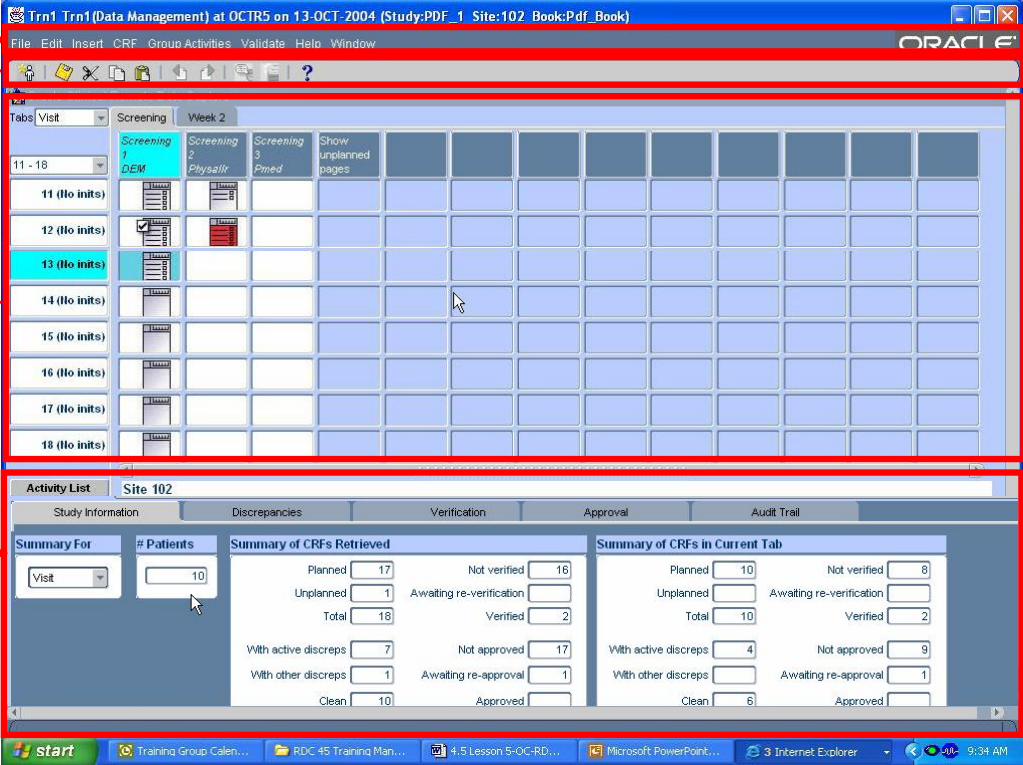
New Terms	The following new terms are introduced in this lesson:
	– **Menu bar** – list of pull-down menus through which users can access OC-RDC features and tools
	– **Toolbar** – list of icons through which users can access OC-RDC features and tools
	– **Spreadsheet** – the main portion of the OC-RDC display. This section is used to display patients and the associated electronic CRFs (eCRFs) The spreadsheet display is divided into rows and columns.
	– **Task Tab** – a portion of the OC-RDC spreadsheet that displays information about the current study and allows the user to:
	▪ Analyze and handle discrepancies
	▪ Verify and approve eCRFs and
	▪ Track revisions to data.
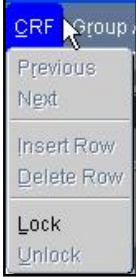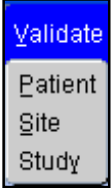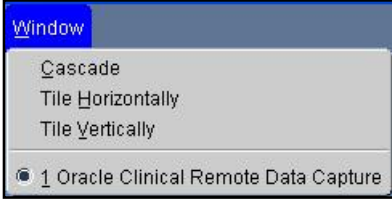
Screen Visual		Notes
The OC-RDC Main Window (The Spreadsheet)	The OC-RDC Main Window (The Spreadsheet)	
Spreadsheet – Training Objectives After completing this lesson, students will be able to: 1. Describe the four primary sections of the Main Window 2. Explain what is represented by each row and column on the OC-RDC spreadsheet 3. Describe how to locate a CRF in the Main Window 4. Describe how to scroll the spreadsheet 5. List three views available and explain how they differ 6. Explain how to display unplanned CRF pages 7. Identify the eCRF icons and describe what each means	After completing this lesson, learners will be able to: 1. Describe the four primary sections of the Main Window 2. Explain what is represented by each row and column on the OC-RDC spreadsheet 3. Describe how to locate a CRF in the Main Window 4. Describe how to scroll the spreadsheet 5. List three views available and explain how they differ 6. Explain how to display unplanned CRFs 7. Identify the eCRF icons and describe what each means	

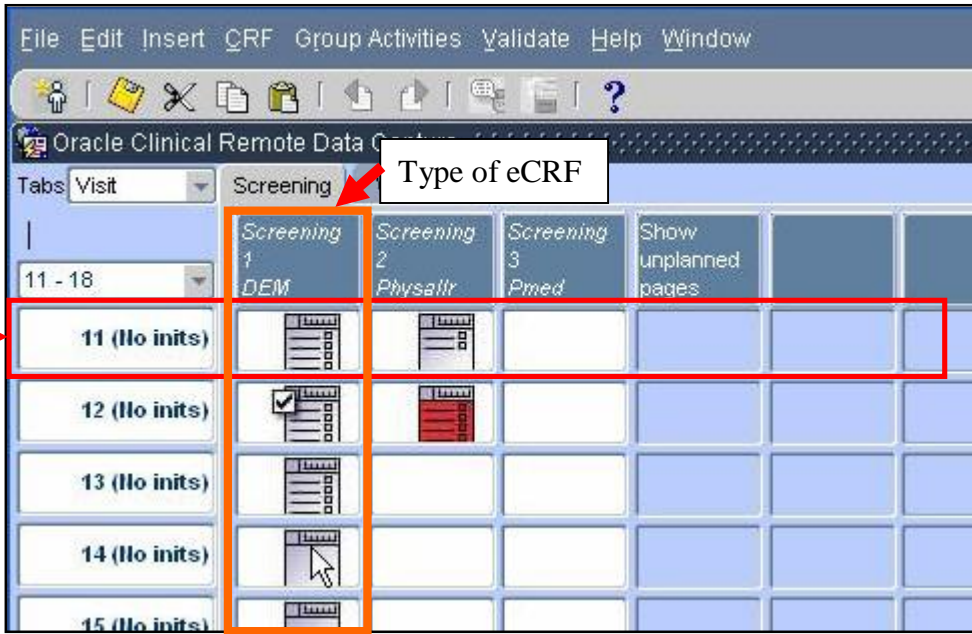| **Screen Visual**		**Notes**
	If your study is configured to use the Activity List it will be displayed automatically when you start an RDC session. The Navigation pane displays the sites and patients available to the OC-RDC user. Its tree-like structure is similar to the hierarchical folder arrangement used in Microsoft Windows Explorer. OC-RDC displays only those components to which the user has access. 	
	You must select an initial workset to display in the RDC Spreadsheet before the system allows you access to the RDC Workspace.	
	To do this, select the site indicated on your OC-RDC bookmark. Then, click on the Show All Data link. 	

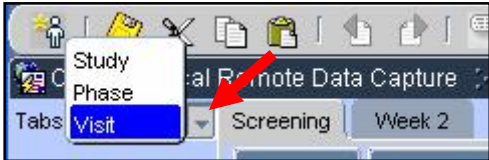| Screen Visual		Notes
	If your study does not use the Activity List, the Search window will display when you log on. The Search window allows the user to specify search parameters that will be used to query the database. The search parameters will determine which patients will be displayed in the Spreadsheet.	
	Using the search window will be explained later in this training. But for now, select the default parameters.	
	To do this, click the OK button.	
	After you have successfully logged on to the study and selected your workset, the RDC Main Window will open and display the cases you have selected.	

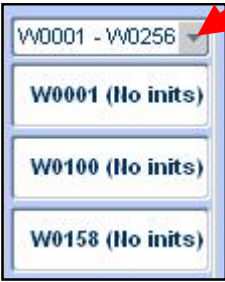| Screen Visual		Notes
	The Main Window contains four primary sections: • The *Menu bar* at the top of the RDC screen • The *Tool bar* located just above the spreadsheet • The *Spreadsheet* in the middle of the RDC screen • The *Task Tabs* at the bottom of the RDC screen	

Menu bar

Toolbar

Spreadsheet

Task Tabs

Screen Visual		Notes
The Menu bar	The Menu bar contains pull-down menus that allow the user to access the tools and features of OC-RDC. File Edit Insert CRF Validate Help Window	
	Click on each pull-down menu as your instructor describes the options available on each menu.	
File Menu	The File menu allows the user to launch a new search, modify a search and change the study. In addition, the File menu allows the user to display the news dialog box, access system reports and print. The File menu is also used to save data, refresh the spreadsheet display and to exit the database.	
Edit Menu	The Edit menu can be used to cut, copy and paste data. Users can also create duplicate data fields within the selected record (useful when working with repeating record groups.) The Edit menu also allows the user to delete a CRF. Users can access the field editor and change preferences through the Edit pull-down menu. Discrepancies and Investigator comments can also be entered using the Edit Menu.	
Insert Menu	The insert menu allows the user to insert a patient, a CRF, a visit, discrepancies and/or Investigator comments to the patient record.	

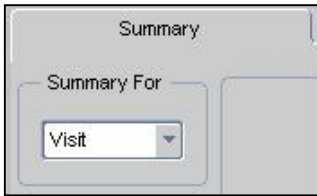| Screen Visual		Notes
CRF Menu	The CRF menu allows the user to navigate quickly to the next or previous CRF within the spreadsheet. Other options on the CRF menu allow the user to insert or delete a row and to lock or unlock a CRF (with appropriate permission level.)	
Validate Menu	The Validate menu allows the user to execute validation checks for a single patient, an entire site or for the entire study.	
Help Menu	The Help menu can be used to access RDC Help topics, access the OC Help system or to see the "About RDC" dialog box.	
Window Menu	The window menu functions similar to other windows applications. Users can control whether windows displays cascade, tile horizontally or vertically. Users can also directly select a window to make it immediately active.	

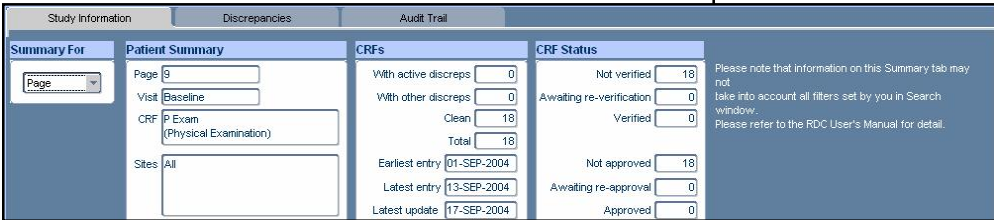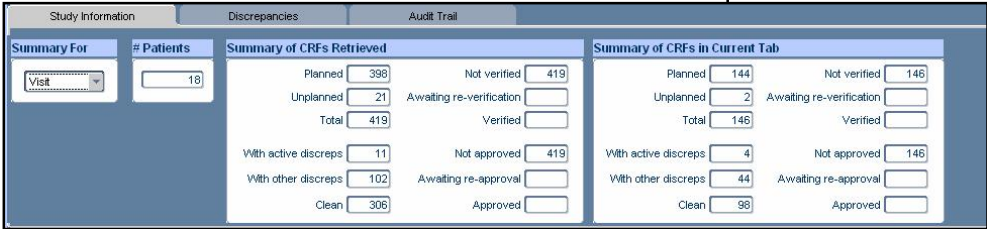| Screen Visual		Notes
The Tool bar	The Tool bar contains icons that allow users to access tools for working with the electronic records in the database. Other icons are used to navigate through the database.	
	Insert Patient icon – Opens the Insert new patient window which allows you to associate a patient with a specific patient number. If there are pending changes, you are prompted to save or discard changes before the Insert New Patient window is displayed.	
	Save icon – Saves all pending changes.	
	Cut icon – In the Data Entry window, moves the contents of the data field in focus to the Windows clipboard.	
	Copy icon - In the Data Entry window, copies the contents of the data field in focus to the Windows clipboard.	
	Paste icon - In the Data Entry window, copies the contents of the Windows clipboard to the data field in focus.	
	Previous CRF - Moves focus to the previous CRF.	
	Next CRF – Moves focus to the next CRF.	

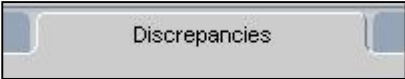| Screen Visual		Notes
The Toolbar (continued)		Investigator comment icon - Opens the Investigator Comment window, which allows you to add a comment relevant to the datapoint currently in focus.
		Manual Discrepancy icon - Opens the Discrepancy for CRF page window, which allows you to add a discrepancy reason, message, and comment for a specific datapoint.
		RDC Help Topics icon - Launches context-sensitive help.
The Spreadsheet	The spreadsheet, or grid, is located in the middle of the RDC screen. This section is used to display patients and their associated eCRFs. The spreadsheet display is divided into rows and columns: • Each **row** represents a patient. • Each **column** represents a specific type of eCRF. • **The intersection of a row and column represents a specific eCRF for a specific patient.** 	

Screen Visual		Notes
	At the top of the OC-RDC spreadsheet you will find a *Tabs* selection pull-down menu. Click on the arrow to choose how eCRFs are displayed on the spreadsheet.	
	RDC has three distinct views from which to view the spreadsheet portion of the application. The three views are Study, Phase and Visit. <table><tr><td>**To see:**</td><td>**Pick this View**</td></tr><tr><td>Entire schedule on a single, scrollable tab page.</td><td>STUDY</td></tr><tr><td>Visits grouped by study phase.</td><td>PHASE</td></tr><tr><td>CRFs grouped by patient visit.</td><td>VISIT</td></tr></table>	
	NOTE: Protocols are set up in the **VISIT** view. The **VISIT** view is the default setting in the system. If you would like to change the view, you must change the view each time you use the application.	

Screen Visual		Notes
Scrolling for Additional eCRFs	In the standard screen resolution (1024 X 780), the spreadsheet can display up to 13 columns of eCRFs. If there are more than 13 columns in the study database, the user can scroll the spreadsheet left or right by: • Dragging the scroll bar found at the bottom of the spreadsheet screen, or • Using the keyboard: Make sure the heading is highlighted, use the <Tab> key to scroll right and the <Shift+Tab> keys to scroll left. • Do not use the left and right arrow keys to scroll.	
Scrolling for Additional Patients	In the standard screen resolution (1024 X 780), the spreadsheet can display up to 8 rows of patients. By default, the spreadsheet displays a sequential range of patients starting with the first patient specified in your search parameters. If there are more than eight patients, you can scroll the spreadsheet up or down by: • Clicking on any *Patient* box and then pressing the up or down arrows on the keyboard. • Using the pull-down menu located at the top of the patient list to select a range of patients. 	
	Practice scrolling through the patient list in the training database as your instructor describes each method of scrolling. Be sure to practice both scrolling methods.	

Screen Visual	Notes
The Task Tabs	The task tabs allow you to analyze, handle discrepancies, approve, verify, and track revisions.

Study Information	Discrepancies	Verification	Approval	Audit Trail

Summary For	# Patients	Summary of CRFs Retrieved		Summary of CRFs in Current Tab	
Visit	14	Planned 73	Not verified 79	Planned 42	Not verified 42
		Unplanned 6	Awaiting re-verification	Unplanned	Awaiting re-verification
		Total 79	Verified	Total 42	Verified
		With active discreps 28	Not approved 79	With active discreps 14	Not approved 42
		With other discreps	Awaiting re-approval	With other discreps	Awaiting re-approval
		Clean 51	Approved	Clean 28	Approved

There are five Task tabs:

1. Study Information

2. Discrepancy

3. Verification

4. Approval

5. Audit Trail

Note: Task tabs are only displayed if the user has the appropriate level of permissions. User who do not have verification or approval rights will not see those tabs.
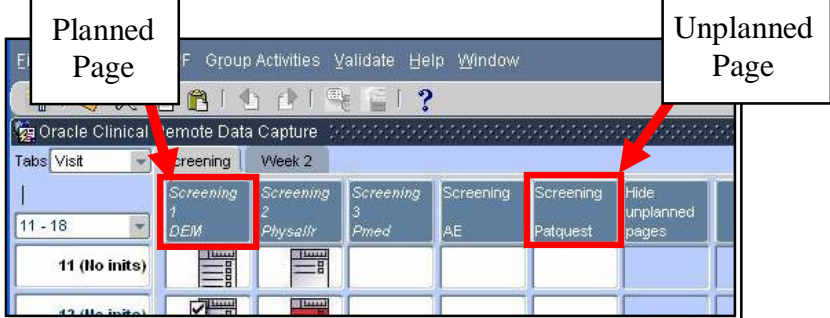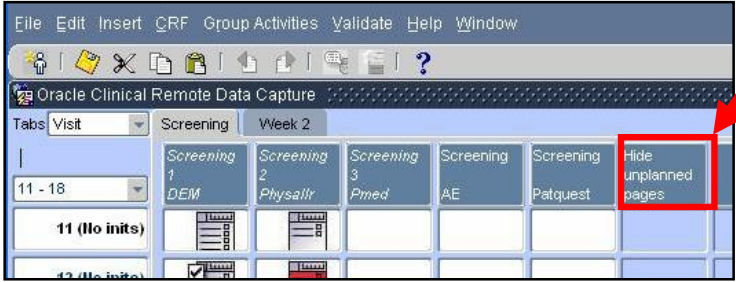
Screen Visual		Notes
The Study Information Task Tab	The Study Information Task tab provides a report of the Spreadsheet data. You can access four views of the Study Information:	

1. Patient view - this view provides information about the currently selected patient.

2. CRF view – this view provides information about the CRFs that is open in the Spreadsheet. The purpose of this information is to give you feedback on CRFs that are at least at an entry status of "Started".
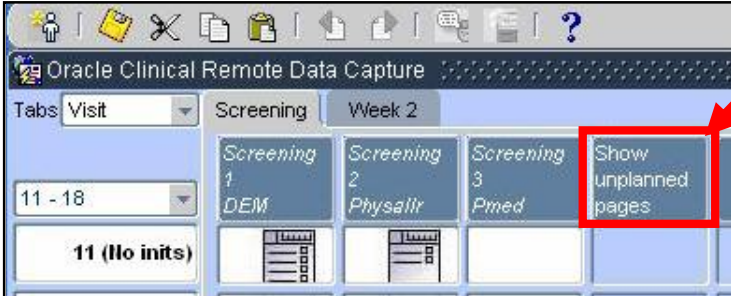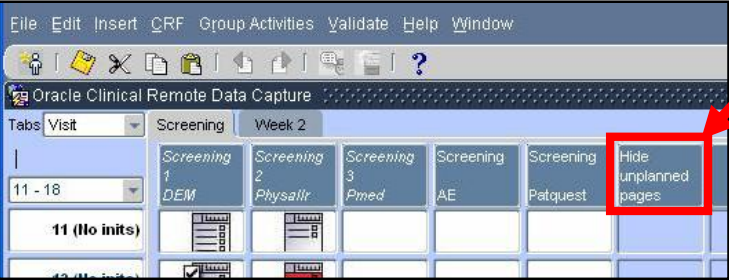
Screen Visual		Notes

3. Page view – this view provides information about the page that is currently in focus in the Spreadsheet. Like the Patient Summary view, this view gives you information about the patient selected. The Page Summary view gives you information about the entire Page column that is currently in focus. Note that this includes information about patients that may be in rows that are not currently displayed in the Spreadsheet.

4. Visit View - this view provides information about the visit that is currently in selected on the Spreadsheet. This view gives you information about the CRF that have been selected as well as displaying information about all of the CRF in the currently selected visit. Note that this includes information about CRFs that may be in rows that are not currently displayed in the Spreadsheet.
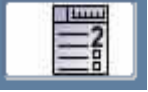
Screen Visual		Notes
Discrepancy Task Tab	The Discrepancy tab provides active feedback on the currently selected CRF. The contents of the Discrepancy tab are entirely dependent on the absence or presence of discrepancies in the active CRF and, if discrepancies are present, the number and status. If the currently active CRF does not contain a discrepancy, either active or closed, a message is displayed in the content area of the tab: "There are no discrepancies for this CRF." When the active CRF page has at least one discrepancy associated with it, the Discrepancy tab is composed of a main sub-tab, named "List" and additional sub-tabs that are only present if there is at least one discrepancy for the current CRF.	

Screen Visual		Notes
Verification Task Tab	The Verification Task tab provides information about the verification status of the currently selected CRF page. If Spreadsheet focus is not on a CRF page, the message "Please select a CRF by clicking on a cell to view verification information" is displayed in the text area of the tab. If a CRF page is selected, its verification information is displayed in the tab. – If the page has never been verified, a single line in the Task tab states that, for the selected patient position, page number, and CRF description: "Current status is 'Not verified'" – If the page has been verified (no matter what its current verification status is), the Task tab provides an extensive set of data that allows you to track all changes made to the verification status of the CRF page.	
Approval Task Tab	The Approval Task tab displays the approval status of the currently selected CRF and provides the mechanism to change its approval status. Note: In general, you must hold the role of "Investigator" or higher in order to alter the approval status of a CRF.	
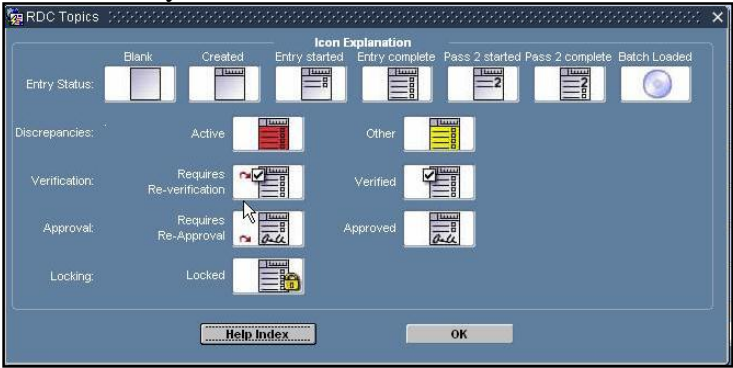
Screen Visual		Notes

Audit Trail Task Tab	The Audit Trail tab displays changes to the currently active CRF. The Audit Trail tab provides extensive information about the history of a given CRF. It displays a list that is based on a significant date, such as the date the CRF was created.
	
	Changes to the selected CRF can be displayed based on:
	  – pre-selected dates, or timepoints, that are significant in the CRF's history, or
	  – date that you designate.
	
	The timepoints include such events as:
	  – CRF creation
	  – approval(s)
	  – verification(s).
	
	When you choose the User Defined item in the drop-down list, the system displays a text field. Enter the date that you wish to use as the start point of the Audit Trail.
	
	The data that is relevant to a CRFs history is arranged in columns that describe where, when, and what data has changed since the date selected in Changes since field(s).	

Screen Visual		Notes
Planned / Unplanned pages	RDC allows users to add patient data for CRFs that are not part of the initial study protocol. These pages are called "unplanned" pages. If unplanned pages are present in the study database, they are displayed in the Spreadsheet just like "planned" pages. 	
	RDC users can toggle between showing and hiding all unplanned pages. To do this, click on the column heading of the first column to the right of the last column with data. This column heading functions as a button that toggles between hiding and showing the unplanned pages. In OC-RDC, the default is to hide unplanned pages. 	
	Try hiding and showing the unplanned pages in the training database.	

Screen Visual		Notes
	When unplanned pages are hidden, the column heading will display "Show unplanned pages." Clicking this column heading will display the unplanned pages.	
	When unplanned pages are displayed, the column heading will display "Hide Unplanned Pages." Clicking this column heading will hide the unplanned pages.	

Screen Visual		Notes
CRF Icons	The icons used to represent a CRF page provide valuable information about the status of the CRF. The CRF icons are used to provide information about the CRF's: • Data Entry Status • Discrepancy Status • Verification Status • Approval Status	
	To see all of the icons used on the OC-RDC database click on <u>RDC</u> Help Topics on the Help menu.	
Data Entry Status	**Blank** - The CRF page is blank.	
	Created - The user has clicked a data cell and opened the data entry window.	
	Entry Started - The user has entered at least one value and saved the CRF as "Incomplete".	
	Entry Complete - The user has entered data for the page and saved the CRF as "Complete".	
	Pass 2 Entry Started - A second data entry user has entered at least one value into the eCRF and saved it.	
	Pass 2 Entry Complete - The second data entry user has entered data for the page and saved it.	

Screen Visual		Notes
	Batch Loaded – The eCRF was loaded during a batch process.	
Discrepancy Status	*White* - There are no open or active discrepancies on the CRF. (Note: There may be closed discrepancies associated with the CRF. There may also be discrepancies not yet identified. These discrepancies will be identified when the CRF is validated.)	
	Red - There is at least one actionable discrepancy on the CRF that is assigned to the user at the site.	
	Yellow - There is at least one open discrepancy on the CRF, but it has been assigned to another user for handling.	
Verification Status	*Verified* – The eCRF has been compared to the source documentation and the data has been confirmed.	
	Re-verification Required – At least one data point in the verified CRF has been modified since the CRF was verified. The CRF must be re-verified.	
Approval Status	*Approved* – The CRF has been reviewed and accepted as valid for the study.	
	Re-approval Required – At least one data point in the approved CRF has been modified since the CRF was approved. The CRF must be re-approved.	
	Locked - The eCRF has been protected to prevent further data entry.	

Screen Visual		Notes
	The RDC *Help* menu contains an explanation of all the eCRF icons that may appear in the OC-RDC data entry spreadsheet. To access the Icon Explanation, click on the Help Menu and select RDC Help Topics. The RDC Icon Explanation window will display automatically. 	

Hands on Exercise: Locating a Specific eCRF

Scenario: You need to check the status of a specific eCRF for a Patient. The CRF in question is for Lab-Urine Form associated with Study Visit 1.

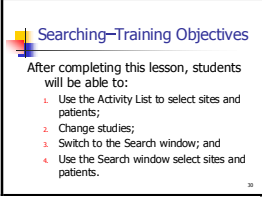| Step	Instructions/Screen Visual	Instructor Notes
	Begin by locating and selecting the patient ID for "My Sample Patient" indicated on your OC-RDC Bookmark.	
	Click on the "Visit 1" tab to display the eCRF associated with Visit 1.	
	If the "Lab-Urine" eCRF is not displayed, click on the column header titled, "Show unplanned pages."	
	Click on the eCRF for the Visit 1 Lab-Urine report for the desired patient.	
	On what date was the specimen collected?	
	Had the patient fasted prior to testing?	
	What was the Glucose result for the specimen?	
	Has this eCRF been verified?	
	Has this eCRF been approved?	

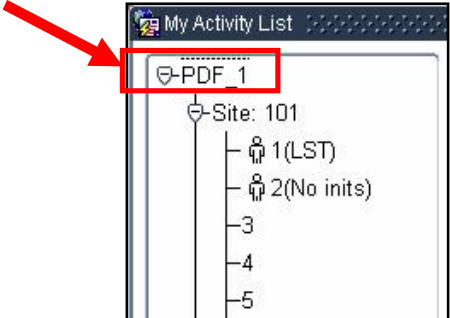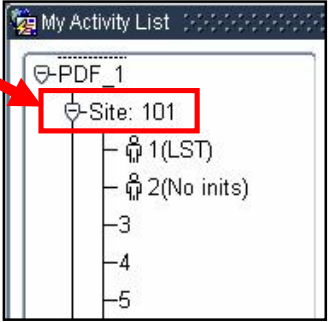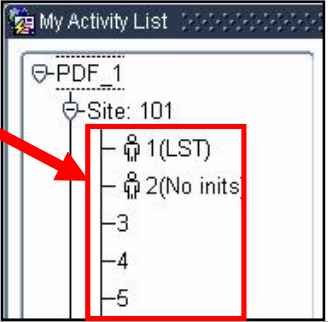| Summary	The OC-RDC main window is composed of four main sections: the file menu, the toolbar; the spreadsheet and the task tabs. Users must be able to navigate around the main window in order to access, view and update individual eCRFs and to handle discrepancies within the CRFs.
Review	1. What are the four primary sections of the OC-RDC Main Window? 2. What is represented by the intersection of a row and a column on the OC-RDC spreadsheet? 3. What two methods can be used to see additional rows and columns on the spreadsheet? 4. List three Tab views available on the OC-RDC spreadsheet and explain how they differ. 5. Describe how to hide and display unplanned pages in the spreadsheet. 6. List the four views available on the Study Information Task Tab found on the OC-RDC spreadsheet.

SEARCHING THE DATABASE

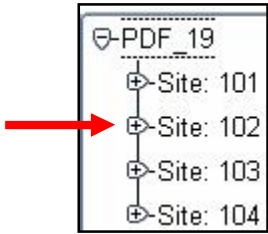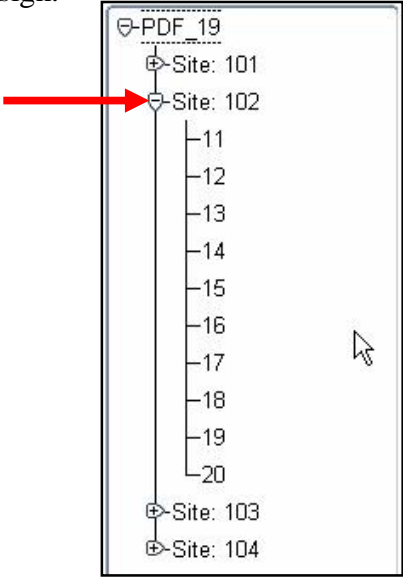| Introduction	This lesson describes the two methods available to select the data necessary for performing common tasks in the OC-RDC database: • Activity List • Search Window Not all studies will employ the activity list feature. This feature is configurable by the system administrator.

Lesson Objectives	After completing this lesson, learners will be able to do the following:
	
	 • Use the Activity List to
	
	   Select sites and patients;
	   Select a data subset;
	   Change studies; and
	   Switch to the Search Window.
	
	 • Use the Search Window to
	
	   Select patients from the study database;
	   Select a data subset;
	   Change studies; and
	   Switch to the Activity List.

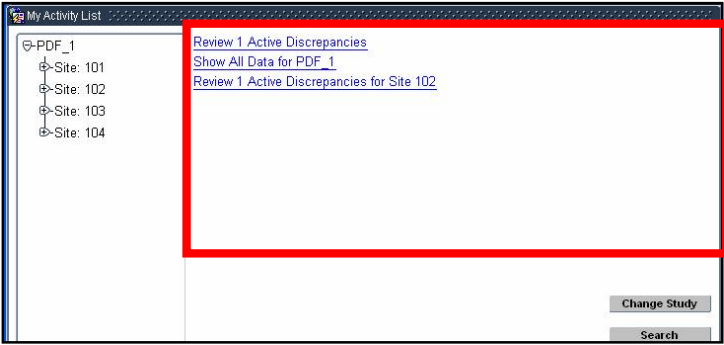|	
New Terms	The following new terms are introduced in this lesson: **Book** - A set of CRFs that are organized in the order that data entry is expected to occur **Site** – A location where study data is collected **Phase** - Protocol components (e.g. pre-treatment, treatment, followup) **Visit** - An instance of treatment. For example, visits may consist of physical examination and medication **Page** - In RDC, page refers to the name or column number of an eCRF, not necessarily corresponding to any physical piece of paper. A page may be longer than a single data entry screen, but you can scroll to see the remainder of the page. A page is usually synonymous with a CRF, but it could be different from a CRF if the CRF is divided into 2 or more data entry modules **Planned Visit** – An expected patient visit that is included in the study protocol **Unplanned Visit** – An instance of patient treatment that is unexpected and not a part of the study protocol **CRF Status** – Selection criteria based on indications of the data entry progress for CRFs (e.g. blank, created, entry started, entry complete, pass 2 started, pass 2 complete) **Discrepancy Status** – Selection criteria based on the presence and type of discrepancies found on CRFs
Background	The Activity List window is a standard RDC feature used to select the task to be accomplished during a RDC session. When you select a task in the Activity List window, the workset necessary to complete that task is automatically displayed in the RDC Spreadsheet. For example, if you select a task, "Review 23 open discrepancies in Site001", the OC-RDC system generates a workset that includes only those CRFs that contain the twenty-three discrepancies and their associated patients. The Activity List window offers an intuitive method of working in RDC. Each task is a descriptive statement that allows the user to automatically select the data needed to perform the task.
Primary function	The Activity List allows the user to navigate directly to the appropriate point in the workflow. Essentially, the Activity List provides a means to start working in RDC without first having to select criteria and parameters in the Search window.

	It consists of: • A list of all of the sites to which the user has access in the current study; • A list of all patients at each site; and • A set of tasks that are specific to the study, a site, or a patient, depending on which is selected.
Alternative to Search window	Each task present in the Activity List corresponds to a specific set of search criteria. When the user selects a task, the associated search criteria are loaded into the Search window behind the scenes. The data that satisfies that query is then automatically displayed in the RDC Spreadsheet. The Activity List window is an alternative to the Search window. When an RDC session is configured to use the Activity List, users can also access the Search window. Because the Activity List uses the Search window to query and display a set of data, when you select the File=>Modify Search menu command, or click the Search button on the Activity List window, the Search window opens with the criteria that were defined by the last task chosen.
The Search window	This lesson also introduces the OC-RDC search window. It details how to specify selection parameters to be used to query the study database for selecting patient data to be displayed. The primary purpose of the Search Window interface is to allow the user to select and display only those data records that match certain criteria. The data that comprise a clinical study can be extensive. The Search tool allows the user to define a manageable amount of data to work with during an RDC session. The Search dialog screen allows the user to combine multiple selection parameters to view a subset of patient data from the study database. Patients can be selected based on a single parameter or multiple parameters. Once a parameter is specified, it remains active in all subsequent searches until cancelled.
	Depending on system configuration, the Search window may be automatically displayed by the OC-RDC system when the user initially logs into the application. The Search window can also be opened by the user. This may be done to initiate a new search or to modify the current search. To begin a new search, click the Search button or select File=>New Search. To modify the current search criteria, click the Search button or select File=>Modify Search.

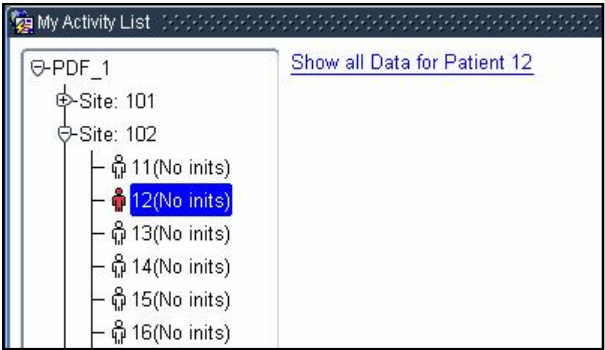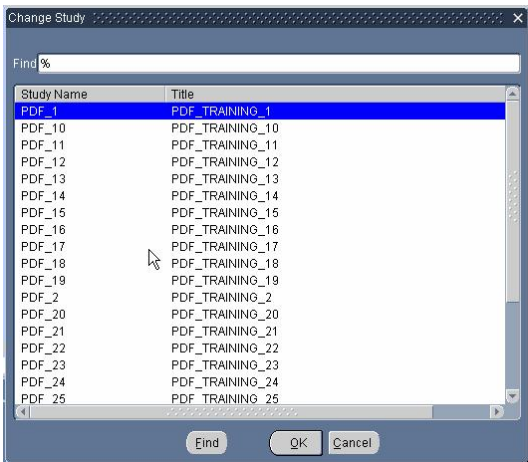| Screen Visual		Notes
Searching the Database	Searching the Database	
Searching–Training Objectives After completing this lesson, students will be able to: 1. Use the Activity List to select sites and patients; 2. Change studies; 3. Switch to the Search window; and 4. Use the Search window select sites and patients.	After completing this lesson, learners will be able to: 1. Use the Navigation pane to select sites and patients; 2. Use the task pane to select a data subset; 3. Change studies; 4. Switch to the Search window; and 5. Use the Search window to select sites and patients for display in the RDC spreadsheet.	

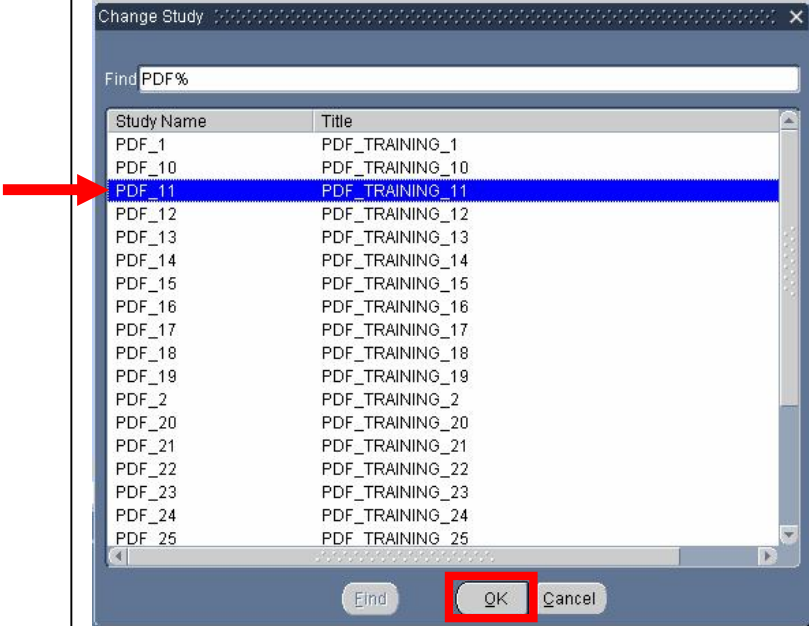| Step	Instructions/Screen Visual	Notes
The Activity List	The Activity List window is displayed automatically when you start an RDC session.	
	You must select an initial workset to display in the RDC Spreadsheet before the system allows you access to the RDC Workspace.	
Navigation Pane	The Navigation pane displays the sites and patients available to the OC-RDC user. Its tree-like structure is similar to the hierarchical folder arrangement used in Microsoft Windows Explorer. OC-RDC displays only those components to which the user has access.	
	The three levels that may be displayed in the Navigation pane are: **1.** Study - the highest level in the hierarchy, there can be only one study present in the Navigation pane.	

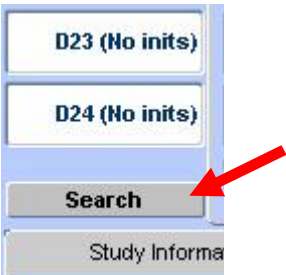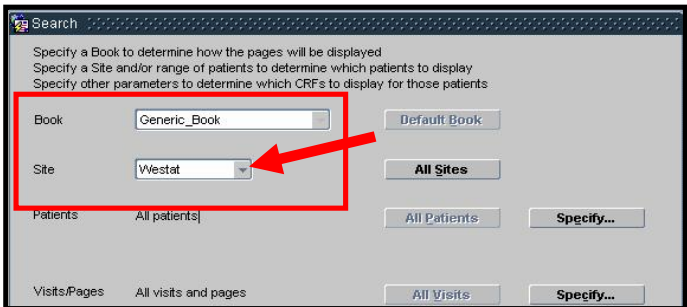| Step	Instructions/Screen Visual	Notes
	2. Site - the intermediate level in the hierarchy, there can be multiple Sites present in the Navigation pane, depending on: ■ the number of sites in the study, and ■ the number of sites to which the user has access	
	3. Patient - the lowest level in the hierarchy, there can be any number of Patient nodes present under each Site node, depending on: ■ the number of patients assigned to the site, and ■ the number of patients to which the user has access	
	Each level within the Navigation pane may have one of three states: • Empty • Collapsed • Expanded	
	An empty data level cannot be expanded or collapsed since there is no data to be shown or hidden.	

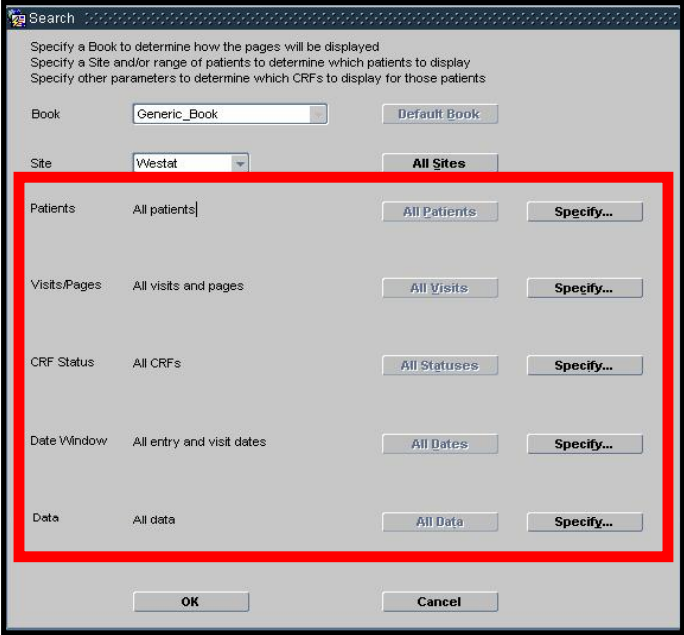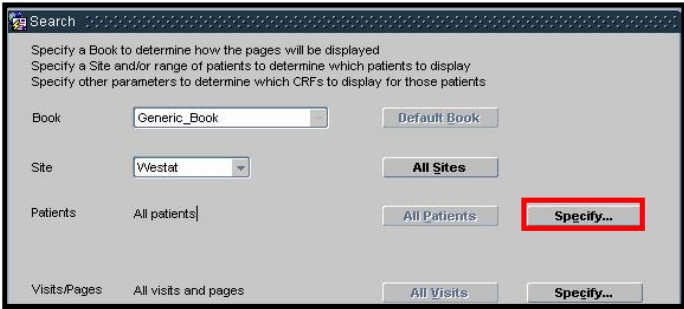| Step	Instructions/Screen Visual	Notes
	If data is located within the data level, the plus symbol will be displayed.	
	To expand the data level and display the sites or patients in that node, click on the plus symbol.	
	Once the data level has been expanded and the sites or patients displayed in the Navigation pane, the symbol will change to a minus sign. This indicates that the data level can be collapsed. To collapse the data level, click on the minus sign.	

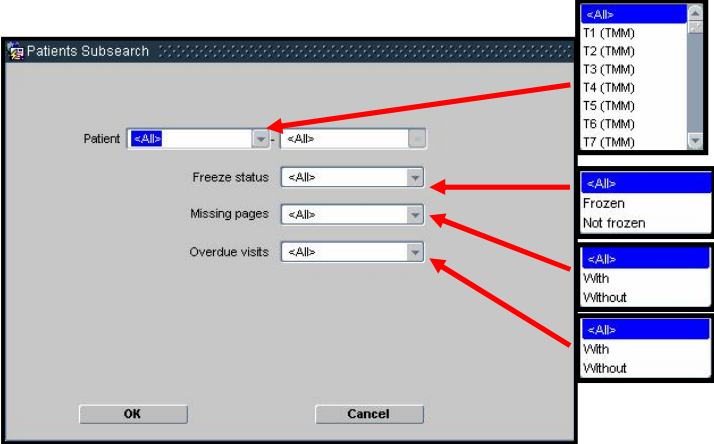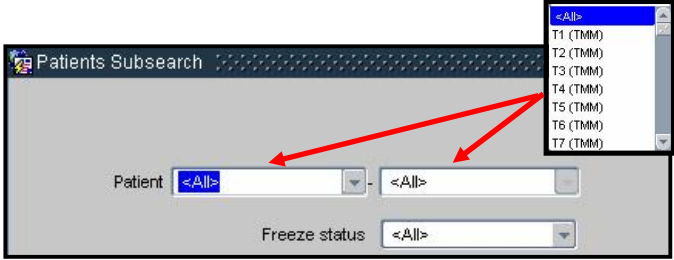| Step	Instructions/Screen Visual	Notes
Task Pane	The task pane displays a list of tasks that are associated with the data level selected in the Navigation pane. As the user selects different levels in the Navigation pane, the set of tasks displayed in the Task pane changes.	
Navigation Buttons	Navigation buttons located in the Task pane, allow the user to: • Change Studies • Search the database • Cancel the task list activity • Obtain context sensitive Help for using the Activity List function.	
Typical Study-Level Tasks	At the study level, users will typically be able to select the following tasks: • Review all open discrepancies for the study • Show all data for the study	
Typical Site-Level Tasks	At the site level, users will typically be able to select the following tasks: • Review all open discrepancies for the selected site	

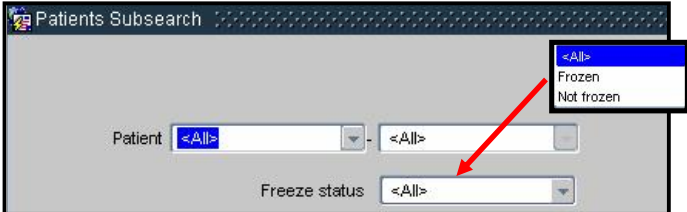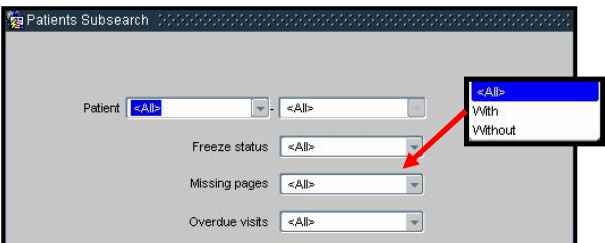| Step	Instructions/Screen Visual	Notes
	• Show all data for the site	
Patient Level	Each patient displayed in the Navigation list is represented by a colored icon indicating the discrepancy information associated with that patient.	
	indicates that there are no discrepancies associated with this patient.	
	indicates that there is at least one discrepancy associated with this patient with the discrepancy status of "Other."	
	indicates that there is at least one active discrepancy associated with this patient. There may also be CRFs with the status of "Other" associated with this patient.	
Select a Task	The Task pane displays the list of tasks that are associated with the currently selected level in the Navigation pane. As you select different levels in the Navigation pane, the set of tasks displayed changes. To enable or activate a task, click on it in the task list. This action closes the Activity List window, populates the Spreadsheet with the relevant data, and prepares RDC so that you can immediately start working on the task.	
	Each task is associated with a specific subset of data. This relationship between a task and the set of data it refers to is called scope.	

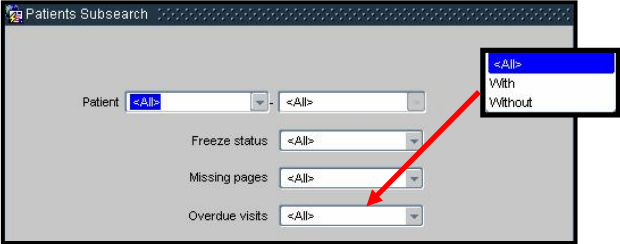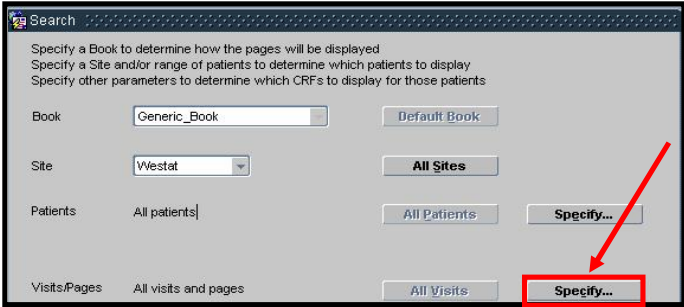| Step	Instructions/Screen Visual	Notes
	Tasks are sorted and displayed based on user role and on the currently selected scope. Therefore, the same tasks are displayed when you select different patients, only the data that is loaded in the Spreadsheet differs. Similarly, the set of tasks for different Site nodes is identical, only the patient data that are loaded in the Spreadsheet differs. 	
	Use the Activity List to Show all CRFs which contain a discrepancy for the site indicated on your training worksheet.	
Changing Studies	If you have access to more than one study, the Change Study button [Change Study] will be displayed in the Activity List window. If you want to open a different study, click the button to open the Change Study window.	
	The Change Study List box will display. 	
	Choose the new study from the list by clicking on it.	

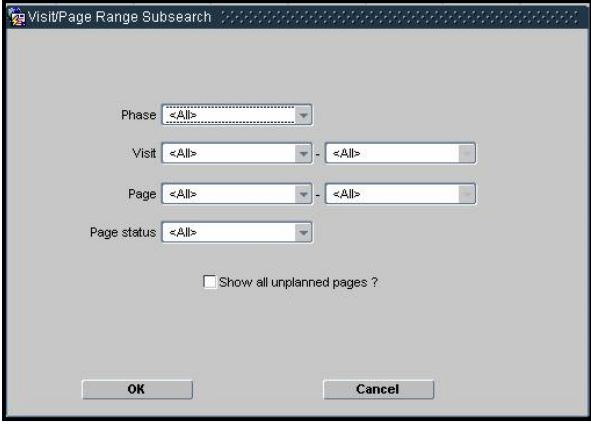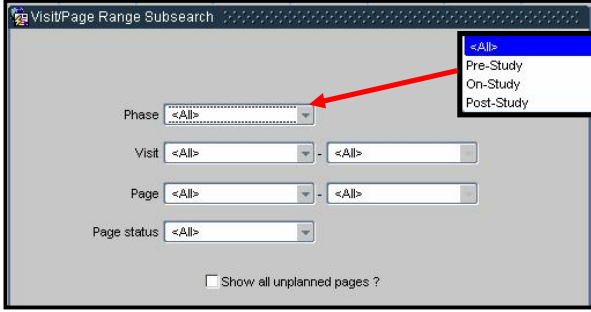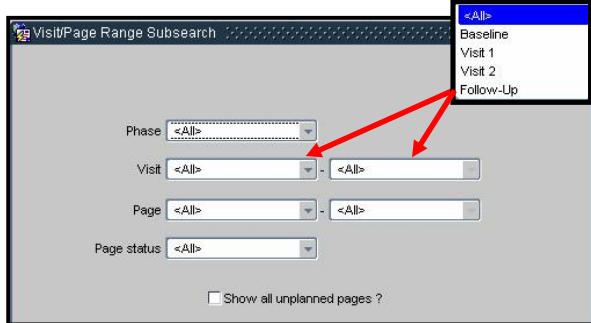| Step	Instructions/Screen Visual	Notes
	Click the OK button. **Change Study** ✕ Find PDF% <table><tr><td>Study Name</td><td>Title</td></tr><tr><td>PDF_1</td><td>PDF_TRAINING_1</td></tr><tr><td>PDF_10</td><td>PDF_TRAINING_10</td></tr><tr><td>PDF_11</td><td>PDF_TRAINING_11</td></tr><tr><td>PDF_12</td><td>PDF_TRAINING_12</td></tr><tr><td>PDF_13</td><td>PDF_TRAINING_13</td></tr><tr><td>PDF_14</td><td>PDF_TRAINING_14</td></tr><tr><td>PDF_15</td><td>PDF_TRAINING_15</td></tr><tr><td>PDF_16</td><td>PDF_TRAINING_16</td></tr><tr><td>PDF_17</td><td>PDF_TRAINING_17</td></tr><tr><td>PDF_18</td><td>PDF_TRAINING_18</td></tr><tr><td>PDF_19</td><td>PDF_TRAINING_19</td></tr><tr><td>PDF_2</td><td>PDF_TRAINING_2</td></tr><tr><td>PDF_20</td><td>PDF_TRAINING_20</td></tr><tr><td>PDF_21</td><td>PDF_TRAINING_21</td></tr><tr><td>PDF_22</td><td>PDF_TRAINING_22</td></tr><tr><td>PDF_23</td><td>PDF_TRAINING_23</td></tr><tr><td>PDF_24</td><td>PDF_TRAINING_24</td></tr><tr><td>PDF_25</td><td>PDF_TRAINING_25</td></tr></table> [Find] [OK] [Cancel]	
	The Activity List for the new study will display automatically. **My Activity List** ⊟-PDF_11 Show all Data for Patient 12 ⊕-Site: 101 ⊕-Site: 102 ⊕-Site: 103 ⊕-Site: 104 [Change Study] [Search] [Cancel] [Help]	
	Note: Only one study can be open in a session at any time. If the user wants to open another study in the current session, the system must first close the current study before opening a second study. The user will be prompted to save any pending changes prior to closing the current study.	

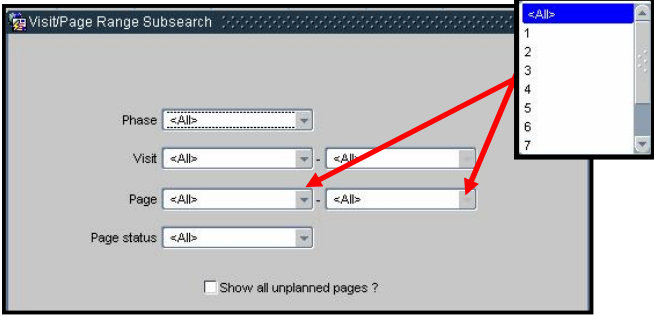| Step	Instructions/Screen Visual	Notes
Switch to the Search Window	If the data subset used for a task is not sufficient or not specific enough, the user can use the Search window to further refine the data subset in use. The Search window gives the user direct access to define search criteria that results in a workset with a specific set of patient data. You can use the Search window to define search criteria that return a workset as broad – all the patient data you have access to – or as narrow – a single CRF – as your task requires.	
The Search Window		
	To launch the Search window, click on the Search button located just below the patient list. 	
Select the Book and the Site	When the Search window opens, the default book and site are the ones to which the user is assigned. Normally, the study will have only one site to choose from unless data is collected from multiple sites. If the user has access to more than one site, the default will be "All sites." Click on the Site pull-down arrow and to choose another site, if available. 	
Establish Search Parameters	The Search dialog box allows you to query the database and select patients based on a number of different criteria	

Step	Instructions/Screen Visual	Notes

	including:
	
	   • Patient identifiers
	   • Visits and pages
	   • CRF Status
	   • Visit and Data Entry Dates
	   • Specific Data matches	

	1. Click on the Specify button to open the Patients subsearch dialog box. 	

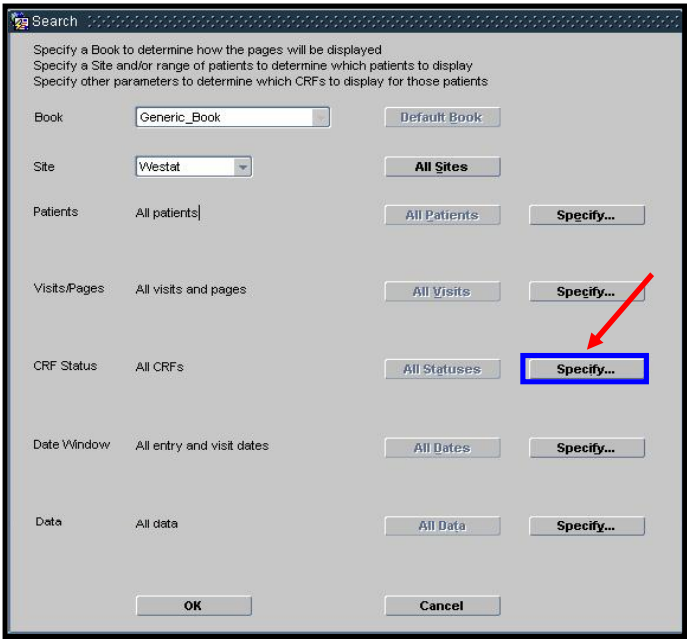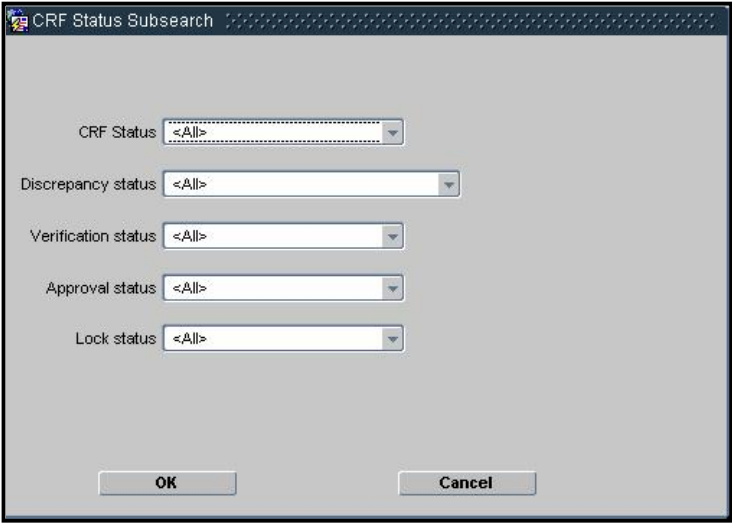| Step	Instructions/Screen Visual	Notes
	2. The Patients Subsearch Dialog Box will open.	
	3. Choose the Patient parameters to select a single patient or a group of consecutive patient IDs from the database.	
Searching for Patients by ID Number	a. To select a single Patient ID, click the first Patient pull-down arrow and select the Patient ID from the list. It is not necessary to change the value of the second field, even though its default value is "All."	
	b. To select a range of Patient IDs, click the first Patient pull-down arrow and select the starting Patient ID from the list. Press <Tab> to move to the next field. Click the pull down arrow and choose the ending Patient ID from the list.	

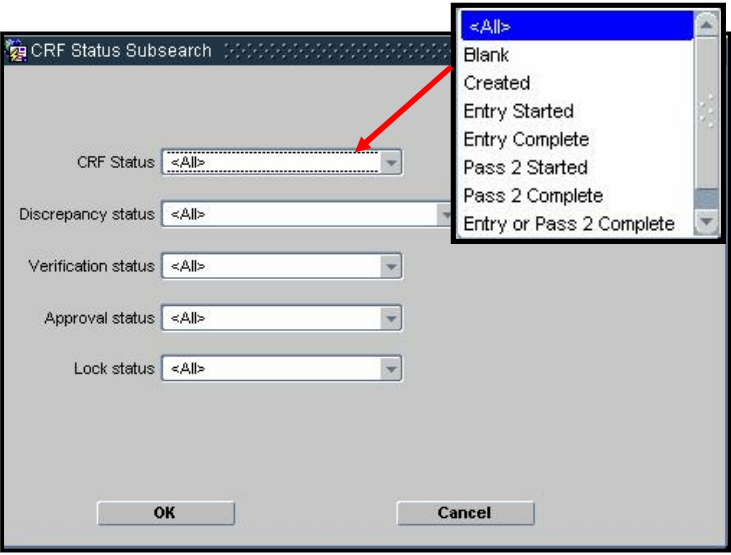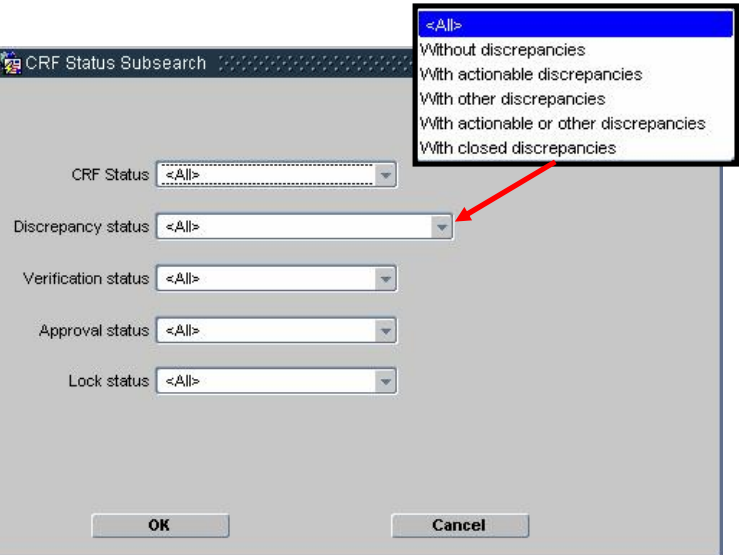| Step	Instructions/Screen Visual	Notes
	Use the Search window to restrict your database view to show only the sample patient on your bookmark.	
Specifying the Freeze Status	4. After you have specified a range of Patient IDs, you can also specify the Freeze status of the cases to be displayed. a. Selecting **<All>** will display all cases within the range of Patient IDs specified. b. Selecting **Frozen** will only display those cases within the Patient ID range where the records are frozen. c. Selecting **Not Frozen** will only display those cases within the Patient ID range where the records are <u>not</u> frozen.	
Specifying the Missing Pages Status	5. After you have specified a range of Patient IDs, you can also specify that the cases to be displayed only include (or exclude) those with missing pages.	
	a. Selecting **<All>** will display all cases within the range of Patient IDs specified regardless of whether the case has missing pages or not. b. Selecting **With** will only display those cases within the Patient ID range where the records contain missing pages. c. Selecting **Without** will only display those cases within the Patient ID range where the records do not contain missing pages.	

Step	Instructions/Screen Visual	Notes
Specifying the Overdue Visit Status	6. After you have specified a range of Patient IDs, you can also specify that the cases to be displayed only include (or not include) those with overdue visits. a. Selecting **<All>** will display all cases within the range of Patient IDs specified regardless of whether the case has overdue visits or not. b. Selecting **With** will only display those cases within the Patient ID range where the records contain overdue visits. c. Selecting **Without** will only display those cases within the Patient ID range where the records do <u>not</u> contain overdue visits.	
	7. Click the **OK** button to close the Patients Subsearch Dialog box and return to the Main Search Dialog Screen.	
Searching for Patients by Visit and/or Pages	8. Click on the Specify button to open the Visits/Pages subsearch dialog box.	
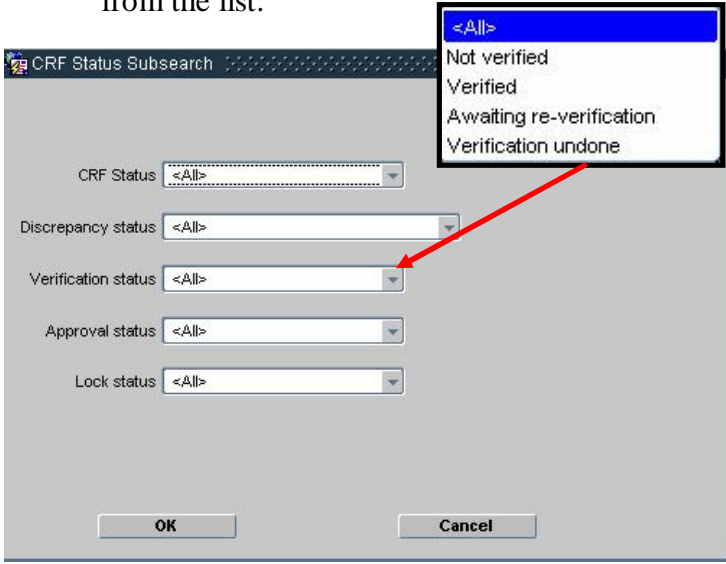
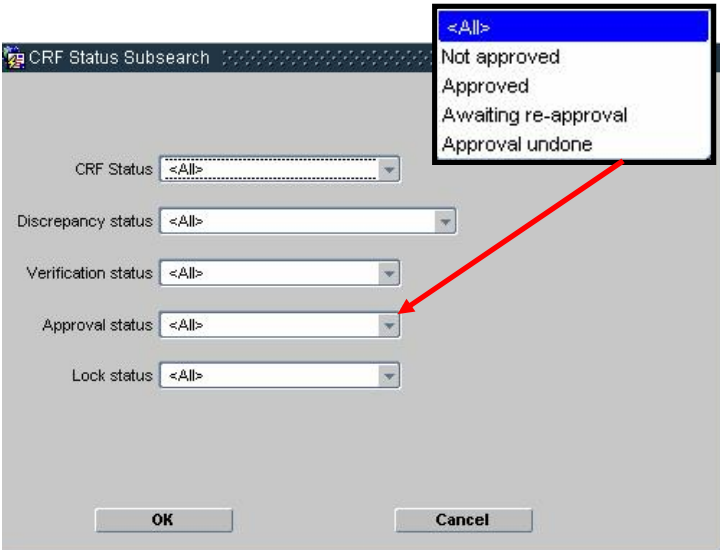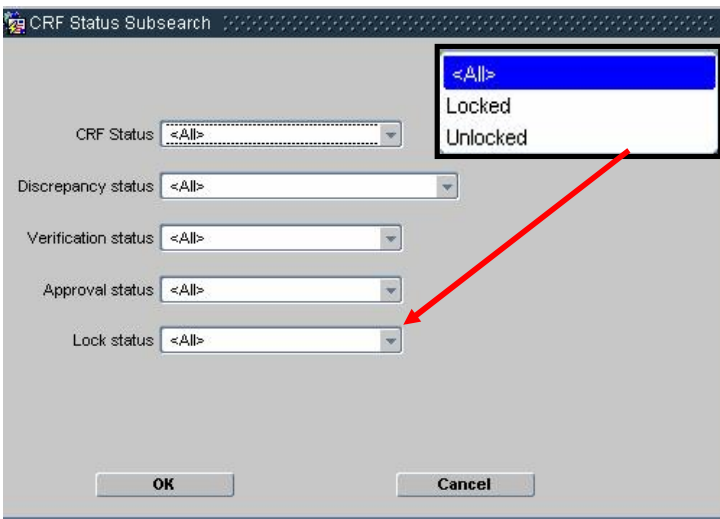| Step	Instructions/Screen Visual	Notes
	9. The Visit/Page Subsearch Dialog Box will open.	
Specifying the Study Phase	10. Choose the Phase parameter to restrict your view to a particular study phase. Click the Phase pull-down arrow and select the Study Phase from the list.	
Specifying the Visit Type	11. Choose the Visit parameter to restrict your view to a particular type of visit or a range of visit types.	

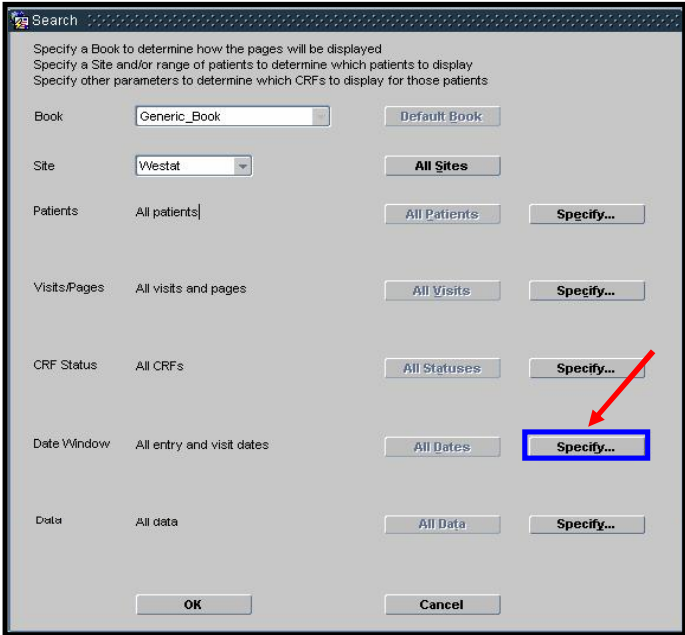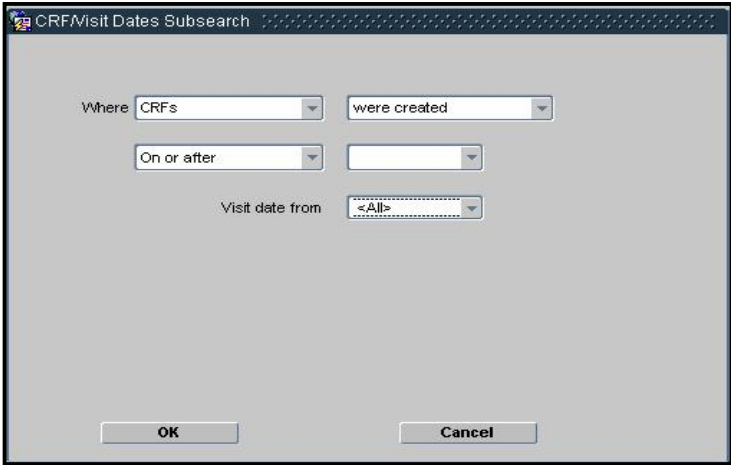| Step	Instructions/Screen Visual	Notes
	a. To select a single visit type, click the first Visit pull-down arrow and select the type of visit from the list. It is not necessary to change the value of the second field, even though its default value is "All." b. To select a range of visit types, click the first Visit pull-down arrow and select the starting visit type from the list. Press \<Tab\> to move to the next field. Click the second Visit pull-down arrow and choose the ending visit type from the list.	
Specifying the Page Type	12. Choose the Page parameter to restrict your view to a particular page or a range of pages. a. To select a single page, click the first Page pull down arrow and select the page number from the list. It is not necessary to change the value of the second field, even though its default value is "All." b. To select a range of pages, click the first page pull-down arrow and select the starting page number from the list. Press \<Tab\> to move to the next field. Click the second Page pull-down arrow and choose the ending page number from the list.	

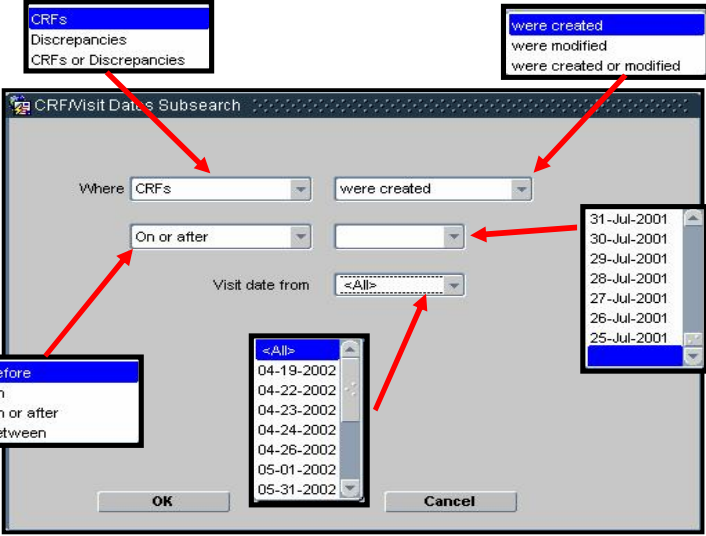| Step	Instructions/Screen Visual	Notes
Specifying the Page Status	13. Choose the Page Status parameter to restrict your view to only planned or unplanned pages. Click the Page status pull-down arrow and select either **Planned** or **Unplanned** from the list. **Note**: When you choose "Unplanned" in the Page status drop-down list, the "Show all unplanned pages?" checkbox will automatically be selected.	
	14. Select the "Show all unplanned pages?" checkbox if you want all unplanned pages to automatically be displayed on the spreadsheet without having to use the "Show/Hide Unplanned Pages" button. **Note:** If you click this checkbox, and the "Page status" parameter is set to show only planned pages a warning message window will be displayed indicating that these two parameters are incompatible.	
	15. Click the **OK** button to close the Visits/Pages Subsearch Dialog box and return to the Main Search Dialog Screen.	

Step	Instructions/Screen Visual	Notes
Searching for Patients by CRF Status	16. Click on the Specify button to open the CRF Status subsearch dialog box.	
	17. The CRF Subsearch Dialog Box will open. CRF Status Subsearch Dialog Box	
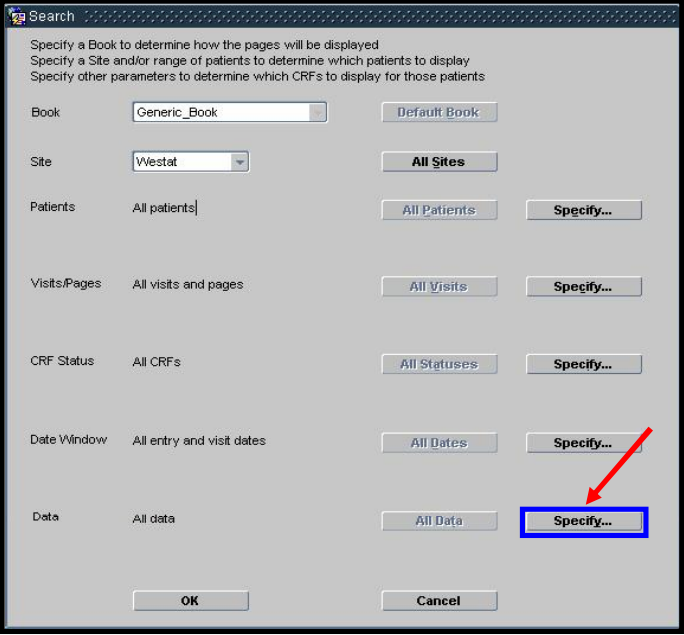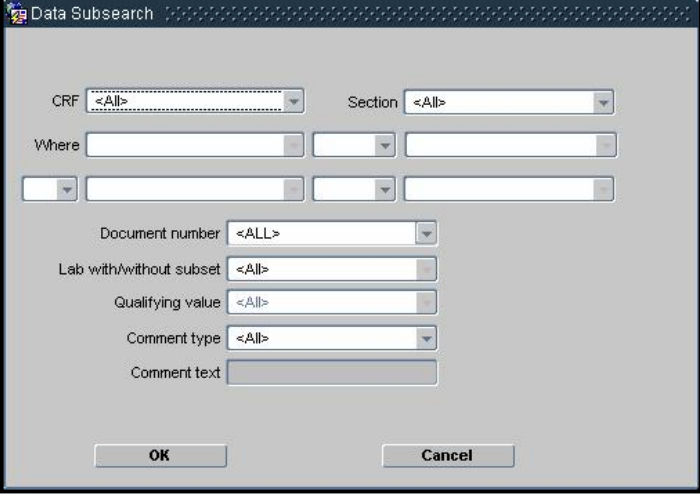
Step	Instructions/Screen Visual	Notes
Specifying the CRF Status	18. Choose the CRF Status parameter to restrict your view to CRFs in various stages of data entry (see list below). Click the CRF Status pull-down arrow and select from the list.	
Specifying the Discrepancy Status	19. Choose the Discrepancy status parameter to restrict your view to CRFs with a particular discrepancy status (see list below). Click the Discrepancy status pull-down arrow and select from the list.	

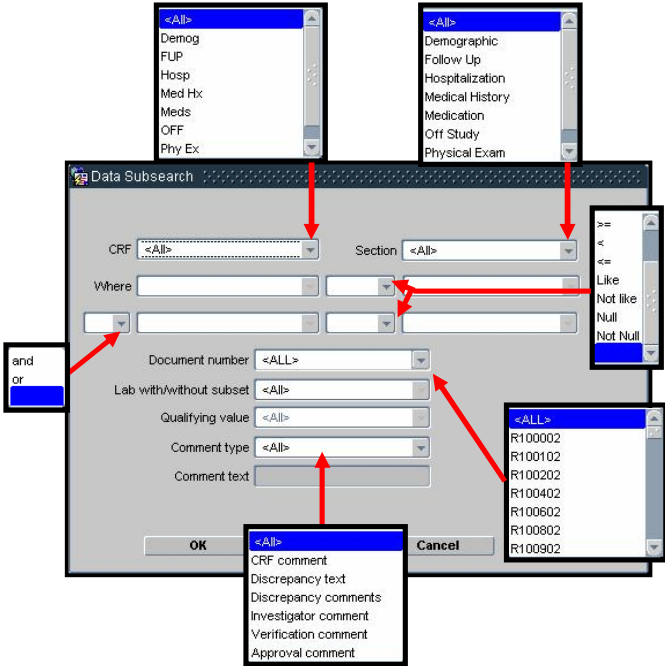| Step	Instructions/Screen Visual	Notes
	Use the Search window to restrict your database view to those CRFs for your patient which contain actionable discrepancies.	
Specifying the Verification Status	20. Choose the Verifcation status parameter to restrict your view to CRFs with particular types of verification status (see list below). Click the Discrepancy status pull-down arrow and select from the list.	
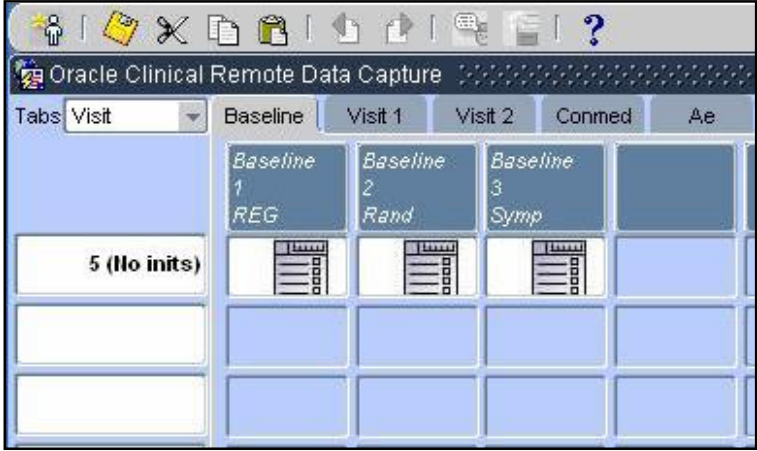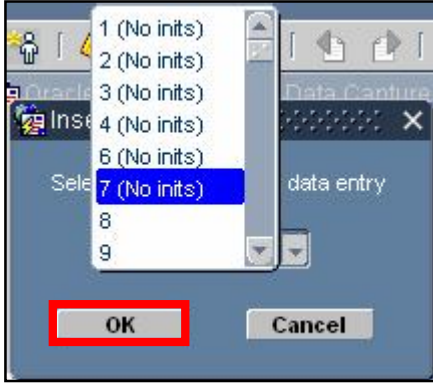
Step	Instructions/Screen Visual	Notes
Specifying the Approval Status	21. Choose the Approval status parameter to restrict your view to CRFs in various states of approval (see list below). Click the Approval status pull-down arrow and select from the list.	
Specifying the Lock Status	22. Choose the Lock status parameter to restrict your view to CRFs that are either locked or unlocked. Click the Lock status pull-down arrow and select from the list.	
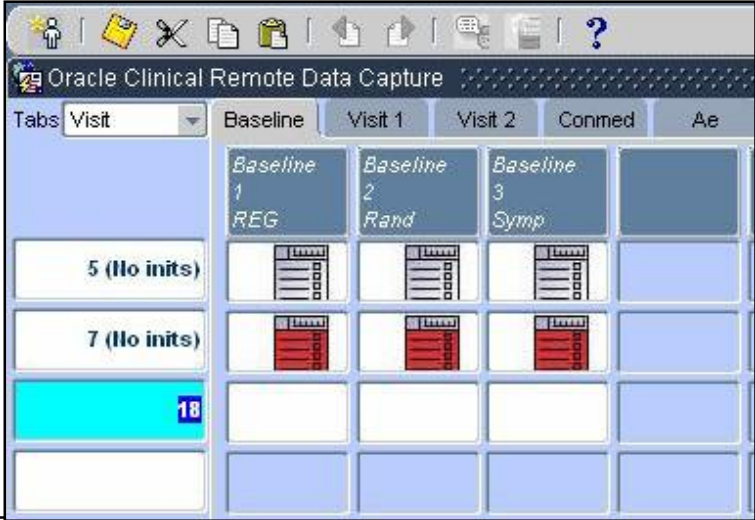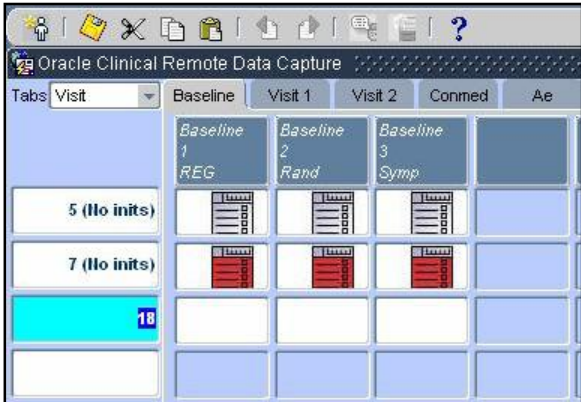
Step	Instructions/Screen Visual	Notes
	23. Click the **OK** button to close the CRF Status Subsearch Dialog box and return to the Main Search Dialog Screen.	
Searching for Patients by Date	24. Click on the Specify button to open the Date subsearch dialog box.	
	25. The CRF/Visit Dates Subsearch Dialog Box will open. **Date Window Subsearch Dialog Box**	

Step	Instructions/Screen Visual	Notes
	26. To search using dates, click on the pull-down arrows and select from each list as indicated below.	
	27. Click the **OK** button to close the CRF/Visit Date Subsearch Dialog box and return to the Main Search Dialog Screen.	
	Use the Search window to restrict your database view to those CRFs entered within the past two days.	

Step	Instructions/Screen Visual	Notes
Searching for Patients by Data	28. Click on the Specify button to open the Data subsearch dialog box.	
	29. The Data Subsearch Dialog Box will open. **Data Subsearch Dialog Box**	

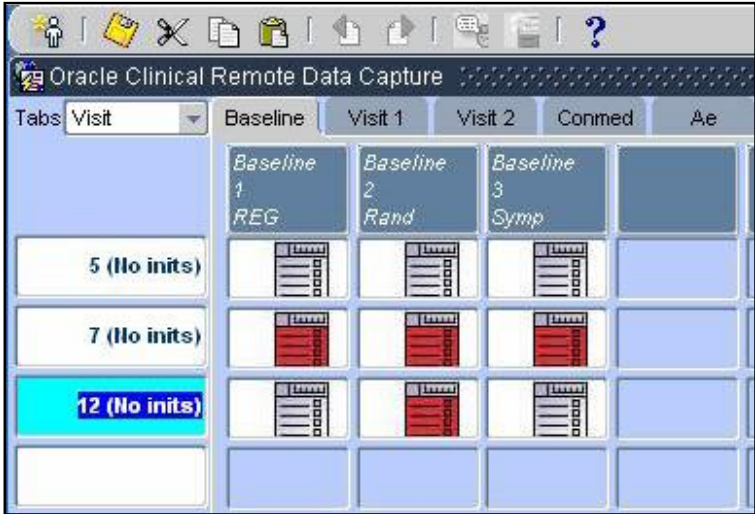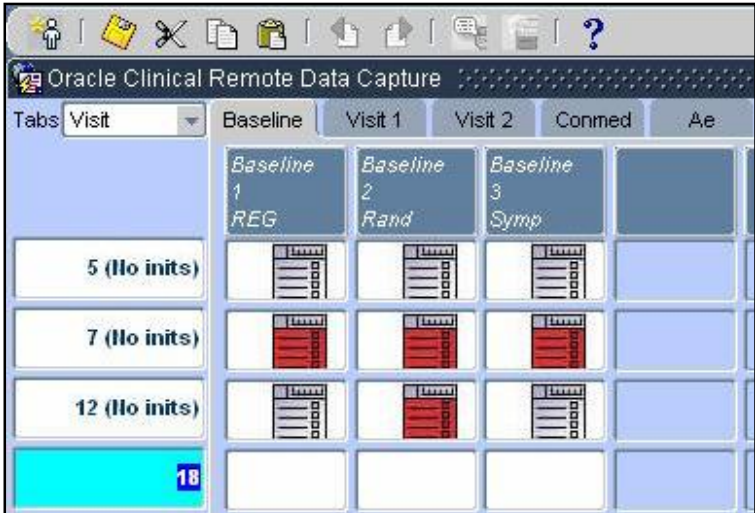| Step	Instructions/Screen Visual	Notes
	30. To search using the data subsearch, click on the pull-down arrows and select from each list as indicated below. **Data Subsearch Dialog Box** 	
	31. Click the **OK** button to close the Data Subsearch Dialog box and return to the Main Search Dialog Screen.	
	32. After you have specified the search parameters, click the OK button on the Main Search screen to execute the search. **Note:** All specified search parameters will be applied when the search is executed. To ensure accuracy of each search, be certain that all subsearch screens are cleared before running subsequent searches.	
	Use the Search window to return your database view to those CRFs for your patient which contain actionable discrepancies.	

Step	Instructions/Screen Visual	Notes
Build a Custom-Selected Patient List	It is possible to view a custom-selected (non-sequential) list of patients on the OC-RDC spreadsheet. This can be useful when you need to refer to several patient records quickly.	
	To build a custom-selected Patient List:	
	Use the Search window to isolate the the first patient you wish to include in your list. (Refer to the Data Entry lesson for detailed instructions.)	
	After you have the single patient displayed in the spreadsheet, click on the next available (blank) patient in the spreadsheet.	
	From the Insert menu, select the next patient ID you wish to include in the spreadsheet display.	
	Click the OK button to add the patient ID to the list.	
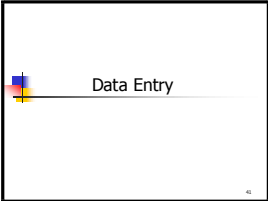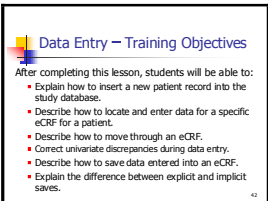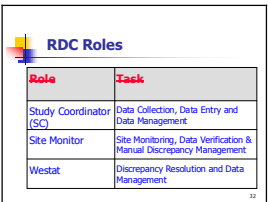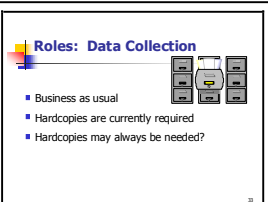
Step	Instructions/Screen Visual	Notes
	Continue building the custom-selected patient list by selecting the next blank row on the spreadsheet and Insert another patient from the list.	
	You can continue until all eight patient rows in the spreadsheet display are filled.	
	Note: Even though the OC-RDC spreadsheet will allow the user to build a custom-selected patient list, the patient IDs must be chosen in sequential order. If the user chooses a patient ID to add to the display that is lower the the bottom patient ID already in the list, the new patient ID will be added to the display but the higher numbered patient ID will be removed from the display list.	
	Here's an example:	
	The existing patient list includes the following patient IDs:	
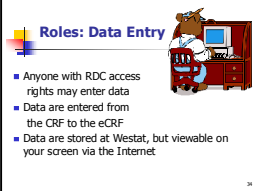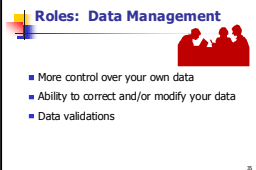
Step	Instructions/Screen Visual	Notes
	The user wishes to add patient ID 12 to the display.	
	After attempting to add the new patient ID to the display, the patient list will look like this: 	
	Note: Patient ID 18 has disappeared from the patient list.	
	To add it back to the display, the user must click in a blank row in the patient list and add the patient ID back into the display list. 	

Summary	The OC-RDC Activity List window is a standard RDC feature used to select the task to be accomplished during a RDC session.

When you select a task in the Activity List window, the workset necessary to complete that task is automatically displayed in the RDC Spreadsheet. For example, if you select a task, "Review 23 open discrepancies in Site001", the OC-RDC system generates a workset that includes only those CRFs that contain the twenty-three discrepancies and their associated patients.

The Activity List window offers an intuitive method of working in RDC. Each task is a descriptive statement that allows the user to automatically select the data needed to perform the task.

The OC-RDC search window can also be used to select parameters to query the study database for selecting patient data to be displayed. The Search window allows the user to define a manageable amount of data to work with during an RDC session. The primary purpose of the Search window interface is to allow the user to select and display only those data records that match certain criteria.

The Search dialog screen allows the user to combine multiple selection parameters to view a subset of patient data from the study database. Patients can be selected based on a single parameter or multiple parameters. Once a parameter is specified, it remains active in all subsequent searches until cancelled. |
| **Review** | 1. Describe the process used to begin entering data into a study database using the Activity List.

2. How can you access the Search window from the Activity List?

3. Which subsearch screen would you use to locate study data from a range of patient IDs?

4. Which subsearch screen would you use to locate all CRFs modified after a particular date?

5. Which subsearch screen would you use to see all CRFs that contain unplanned pages?

6. Which subsearch screen would you use to select all CRFs containing discrepancies that are awaiting verification? |
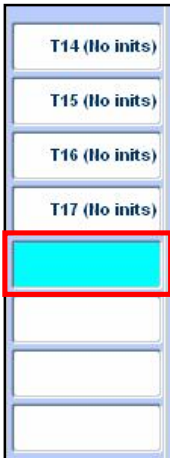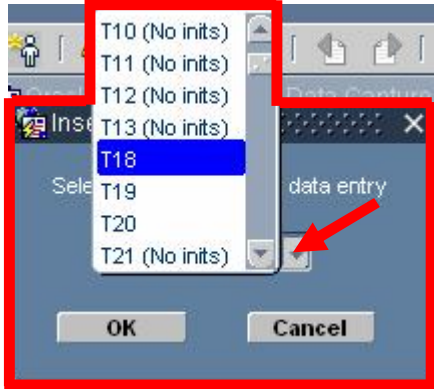
Data Entry
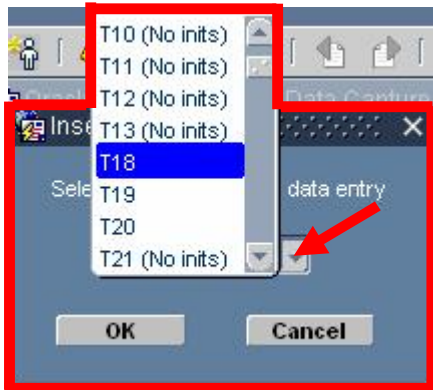
Introduction	Basic data entry in OC-RDC is accomplished using the RDC spreadsheet and the Data Entry screen. Each CRF has a unique data screen designed to collect all of the essential data found on the paper Case Report Form. When a user clicks on an existing eCRF in the RDC spreadsheet, the Data Entry screen for that eCRF opens automatically. Clicking on a blank cell in the RDC spreadsheet automatically creates a new eCRF and opens the Data Entry screen for that eCRF. Initial data entry begins with completing the required header information in the eCRF. After the header information the remaining data fields can be completed and saved to the study database.
Lesson Objectives	After completing this lesson, learners will be able to: – Explain how to insert a new patient record into the study database. – Describe how to locate and enter data for a specific eCRF for a patient. – Describe the three ways to enter a visit date. – Describe how to move through the eCRF. – Describe how to save data entered into an eCRF. – Explain the difference between explicit and implicit saves.
New Terms	The following new terms are introduced in this lesson: – **Mandatory Field Discrepancy –** A required data field was left blank – **Field Length Discrepancy –** The text or value entered into the data field exceeds the number of spaces expected – **Precision Discrepancy –** The numerical value entered contained more decimal places than is required by the eCRF – **Data Type Discrepancy –** The data type entered does not match the expected data type (e.g., numeric vs. character, numeric vs. date, etc.) – **Upper and Lower Bounds Discrepancy –** The value entered falls outside of the expected value range – **Discrete Value Group (DVG) Discrepancy** - The value entered is not in the specified List of Values – **Discrete Value Group Subset Discrepancy** - The value entered is in the base DVG, but not in DVG subset – **Partial Date Discrepancy** - The date entered was not complete
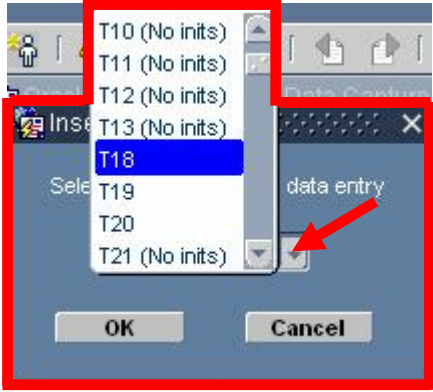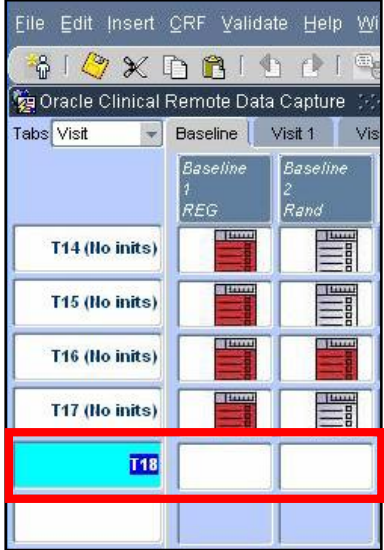
Screen Visual		Notes
Data Entry	Data Entry	
Data Entry – Training Objectives After completing this lesson, students will be able to: • Explain how to insert a new patient record into the study database. • Describe how to locate and enter data for a specific eCRF for a patient. • Describe how to move through an eCRF. • Correct univariate discrepancies during data entry. • Describe how to save data entered into an eCRF. • Explain the difference between explicit and implicit saves.	After completing this lesson, learners will be able to: – Explain how to insert a new patient record into the study database. – Describe how to locate and enter data for a specific eCRF for a patient. – Describe the three ways to enter a visit date. – Describe how to move through the eCRF. – Correct univariate discrepancies during data entry – Describe how to save data entered into an eCRF. – Explain the difference between explicit and implicit saves.	
RDC Roles 	Role	Task
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Study Coordinator (SC)	Data Collection, Data Entry and Data Management
Site Monitor	Site Monitoring, Data Verification & Manual Discrepancy Management
Westat	Discrepancy Resolution and Data Management		Access and permissions within RDC are determined based on your role in the project. **Study Coordinators** typically are responsible for data collection, data entry and some data management tasks. **Site Monitors** typically are responsible for site monitoring, data verification and manual discrepancy management. **Westat Data Managers** typically are responsible for discrepancy resolution and other data management tasks.	
Roles: Data Collection • Business as usual • Hardcopies are currently required • Hardcopies may always be needed?	When it comes to data collection tasks, using RDC is "business as usual." There are few if any changes to your standard data collection procedures. Hardcopies of CRFs and other documentation must still be maintained. In fact, hard copies of all documentation may always be required to be on file.	

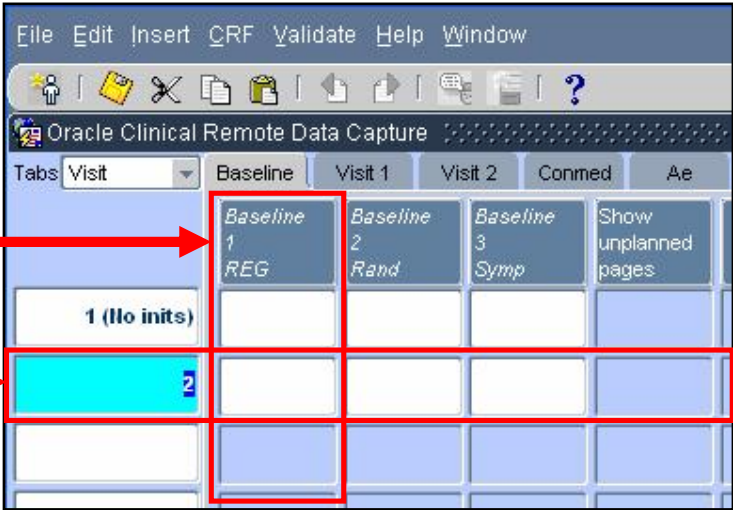| Screen Visual		Notes
Roles: Data Entry ■ Anyone with RDC access rights may enter data ■ Data are entered from the CRF to the eCRF ■ Data are stored at Westat, but viewable on your screen via the Internet	Anyone with access to RDC will be granted rights to conduct data entry. During data entry, required information from the CRF will be entered into the eCRF in RDC. The data captured in OC-RDC is stored at Westat, but is viewable on your screen via the Internet.	
Roles: Data Management ■ More control over your own data ■ Ability to correct and/or modify your data ■ Data validations	Advantages of RDC include: • More control over your site data • The ability to correct and modify your data • The ability to perform data validations from your site	
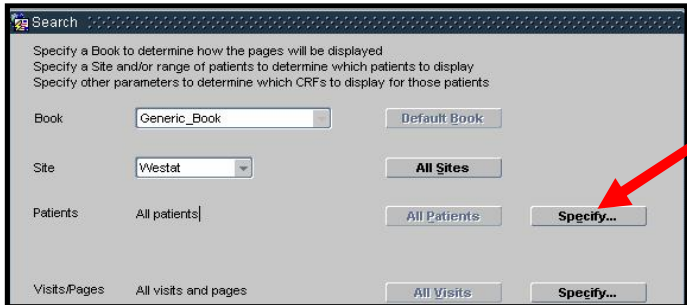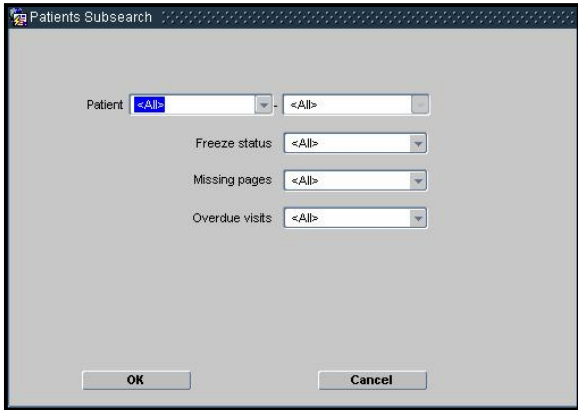
Action	Steps	Notes
Data Entry for a New Patient	Before entering data for a new patient, you must initialize that patient's record in the database spreadsheet. Only Patient IDs that have been activated in the database by Westat can be initiated in OC-RDC. Users cannot create patient IDs in OC-RDC. Westat will provide your site with a list of activated IDs before the start of the study. If you attempt to enter data for a new patient and are not able to find the patient ID in the database, first confirm that the Patient ID is valid. If it is, contact your Westat study representative to resolve the problem.	
Insert a Patient Record	There are three ways to Insert a new patient record: 1. Direct Entry into the Patients List 2. Use the Insert Patient Icon 3. Access the Insert Patient function from the Insert pull-down menu.	

Version 09/27/2005
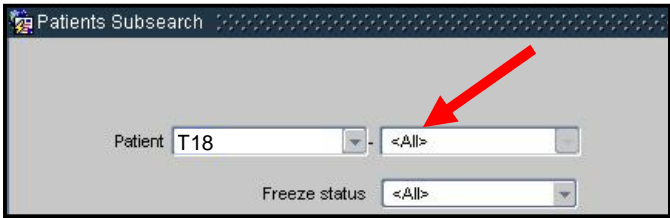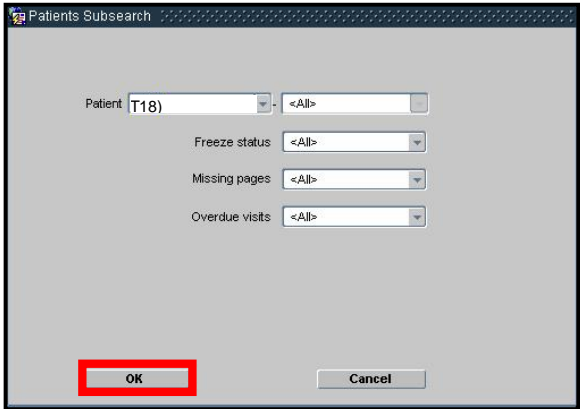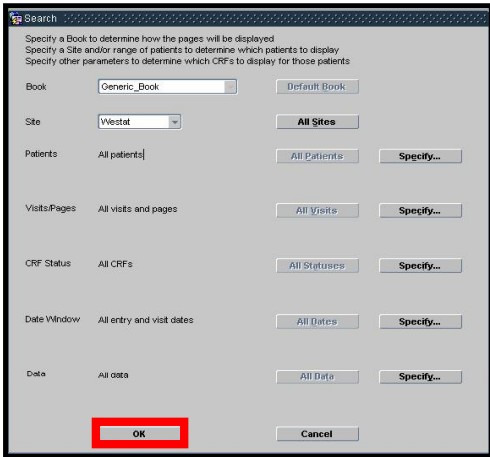
Action	Steps	Notes
	To add a new patient directly to the patient list:	
Direct Entry into the Patient List	1. Scroll down until you come to the first empty Patient box in the Patient ID column. Click in the empty box.	
	2. The Insert new patient dialog box will open. Click on the down arrow. Patient IDs that are currently available for this study will be displayed in the pull-down list. Choose a patient number from the pull-down menu.	
	3. Click the OK button ![OK] to add the new patient number to the patient list.	
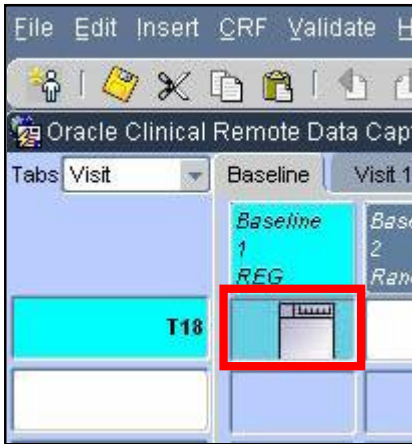
Action	Steps	Notes
	To add a new patient using the Insert Patient Button:	
Use the Insert Patient Icon	1. Click on the Insert Patient button on the toolbar	
	2. The Insert new patient dialog box will open. Click on the down arrow and choose a patient number from the pull-down menu	
	3. Click the OK button [OK] to add the new patient number to the patient list.	
	To add a new patient using the Insert menu:	
Insert a Patient from the Insert Pull-down Menu.	1. On the Insert menu, select Patient.	
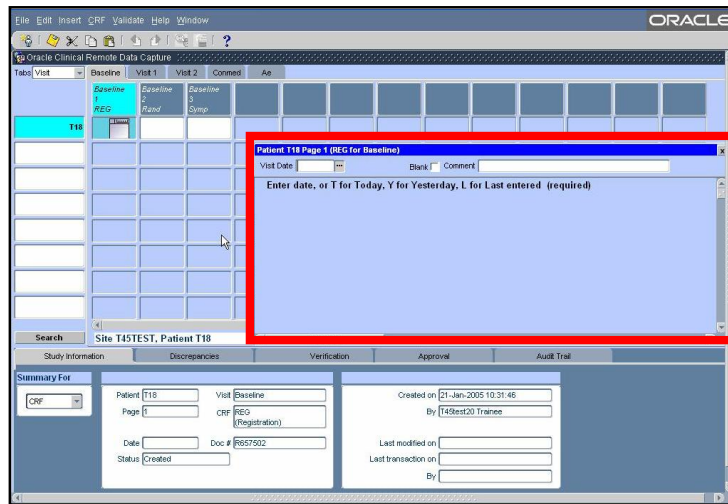
Action	Steps	Notes
	2. The Insert new patient dialog box will open. Click on the down arrow and choose a patient number from the pull-down menu.	
	3. Click the OK button [OK] to add the new patient number to the patient list.	
	The new Patient ID will appear in the Patient box and empty cells will appear on the Patient's row.	
	Practice inserting a new patient using any of the methods shown above. ***Refer to your OC-RDC bookmark training case #1.***	

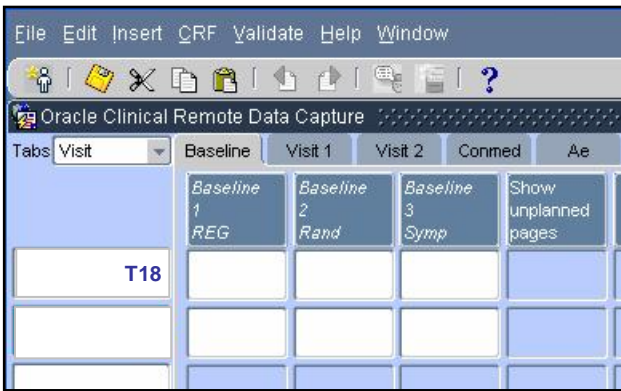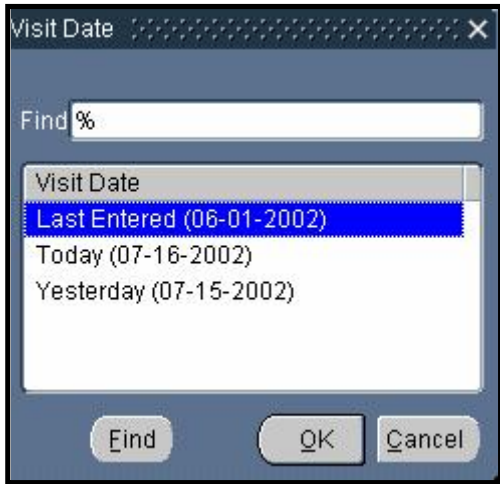| Action	Steps	Notes
Data Entry on an eCRF	Remember, each *column* in the spreadsheet represents a type of eCRF. An abbreviated title for the eCRF is shown in the column header. *Rows* in the spreadsheet represent patients. A *cell* in the spreadsheet represents a specific eCRF for a specific patient. At the beginning of the study, all cells in the spreadsheet are empty. White cells are available for data entry. 	
Isolate Your Patient in the OC-RDC Spreadsheet	**Note:** All specified search parameters are applied each time a search is executed. To ensure accuracy of each search, be certain that all subsearch screens are cleared before running a new search.	
	Launch the Search window, by clicking on the Search button located just below the patient list. 	

Action	Steps	Notes
	1. Click on the Specify button to open the Patients subsearch dialog box.	
	2. The Patients Subsearch Dialog Box will open.	
	3. Choose the newly-inserted patient ID from the first pull-down list.	
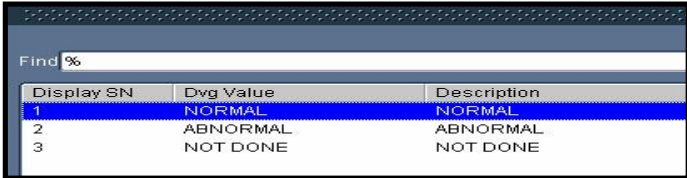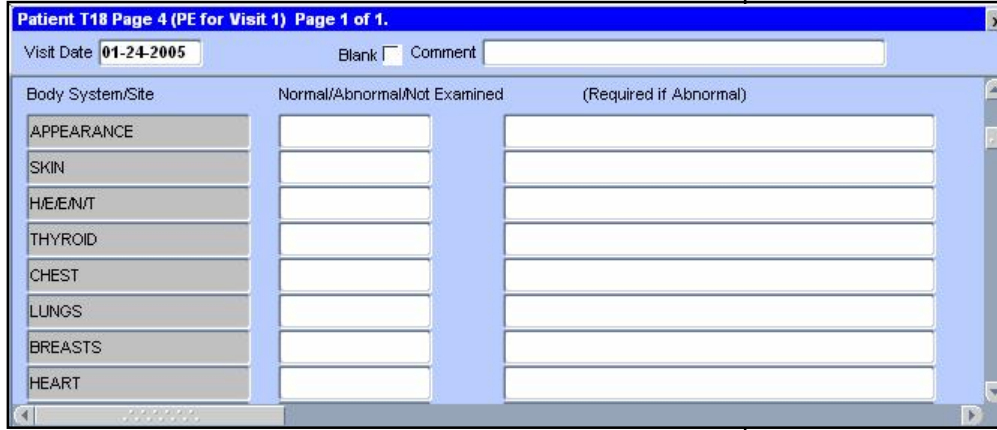
Action	Steps	Notes
	4. Check to ensure that the second pull-down list specifies <All>. *(screenshot: Patients Subsearch — Patient T18 - <All>, Freeze status <All>)*	
	5. Click the **OK** button to close the Patients Subsearch Dialog box and return to the Main Search Dialog Screen. *(screenshot: Patients Subsearch — Patient T18), <All>, Freeze status <All>, Missing pages <All>, Overdue visits <All>, OK / Cancel)* **Note:** All other search parameters in the Patient subsearch window should specify <All>.	
	6. After you have specified the Patient subsearch parameters, click the OK button on the Main Search screen to execute the search. *(screenshot: Search window — Book Generic_Book, Site Westat, Patients All patients, Visits/Pages All visits and pages, CRF Status All CRFs, Date Window All entry and visit dates, Data All data, OK / Cancel)*	
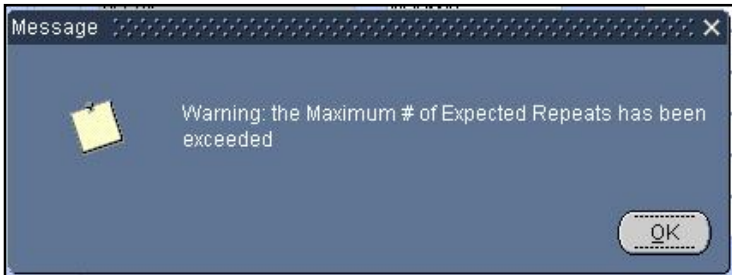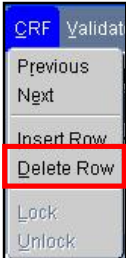
Action	Steps	Notes
	7. The Main Spreadsheet will automatically redraw to show only the single patient you selected.	
	Note: Isolating a single patient on the Spreadsheet display will help you avoid accidentally modifying any existing patients in the study database.	
	Practice isolating the new patient you just added using the Patient subsearch window.	
Opening a Data Entry Form	To begin data entry, locate the study visit that contains the CRF that you want to enter by clicking on the tabs at the top of the data entry spreadsheet.	
	Click the empty cell at the intersection of the Patient ID and the CRF you want to enter. The system initializes and opens the data entry form. A created record icon appears in the spreadsheet cell as shown below.	
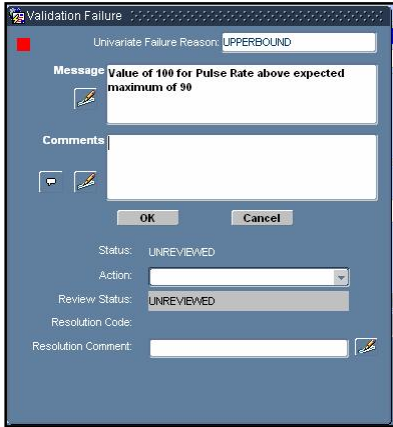
Action	Steps	Notes
	The eCRF data entry form will open.	
	Open a new registration form for data entry by clicking the intersection of the row representing the new patient you just inserted and the column representing the registration eCRF.	
eCRF Data Entry	Begin data entry by entering or changing values in the header at the top of the data entry window.	
Entering a Date into the eCRF	To enter the CRF date, click in the Visit Date field and type the date you want to assign to the CRF.	
Date Formatting in RDC	Dates can be formatted in RDC in one of four ways. The selected date format effects the way dates are displayed on the screen and the format that must be followed when dates are entered into the system.	

Name	Format	Example	Meaning
US	MM-DD-YYYY	12-01-02	December 1, 2002
European	DD-MM-YYYY	12-01-02	12 January, 2002
Swedish	YYYY-MM-DD	12-01-02	2012, January 2
Standard	DD-Mon-YYYY	12-Jan-02	12 January, 2002
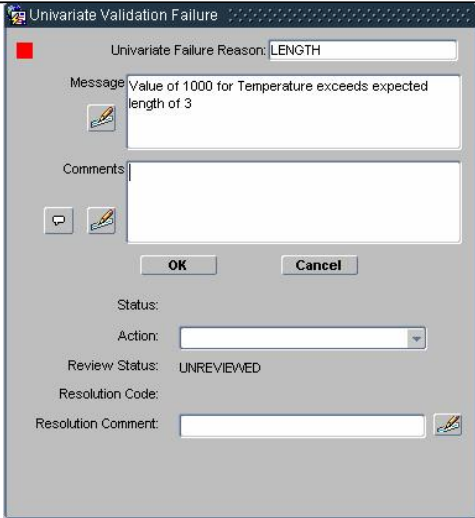
Action	Steps	Notes
	The RDC system administrator sets the date format for all studies within the database. **The default setting is the US date format.**	
	NOTE: When entering dates in RDC, you can use: • Hyphens (12-15-04); • Slashes (12/15/04); or • Blank spaces between numbers (12 15 04)	
	You can also use shortcuts to enter the date: • Type T to enter Today's Date • Type Y to enter Yesterday's Date • Type L to recall the Last Date Entered. Note: You are able to backdate the eCRF in OC-RDC. However, doing so may produce a discrepancy.	
	You can also choose the date by clicking on the ellipsis (…) button. **Patient T18 Page 1 (REG f** Visit Date [ ] [...]	
	A box appears with a list of dates from which you can choose. These dates include previously entered Visit Dates, Today's date and Yesterday's date. Visit Date ✕ Find % Visit Date Last Entered (06-01-2002) Today (07-16-2002) Yesterday (07-15-2002) Find OK Cancel	
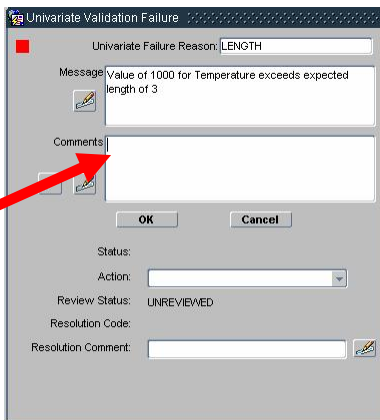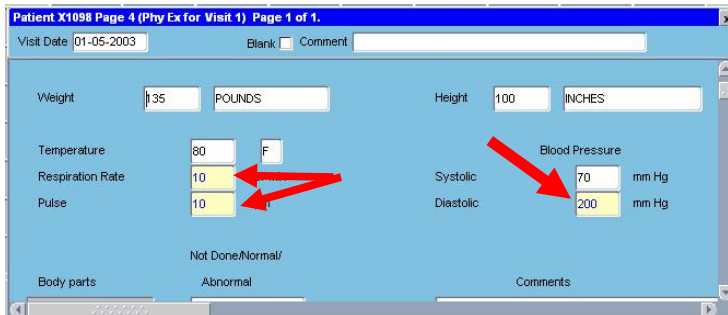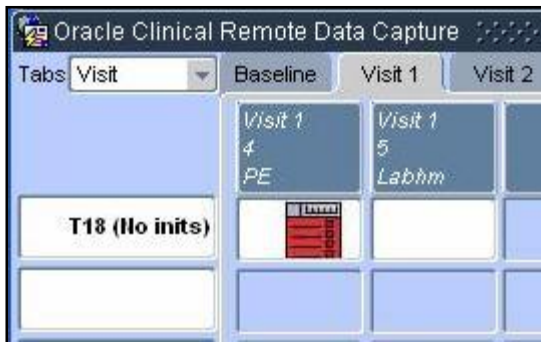
Action	Steps	Notes
Creating a Blank eCRF	If you want to indicate that you are creating a CRF with no data, click in the check box labeled **Blank**. **Patient T18 Page 1 (REG for Baseline)** Visit Date 04-12-2005 ··· Blank ☐ Comment [ ]	
	If the **Blank** checkbox is selected, you will not be able to enter data into the CRF fields. This feature should only be used if you have study-specific instructions to do so. For example, your study manager might want you to do this for every "expected" CRF that was not collected in order to confirm that you know the CRF is not available.	
Using the Comment Field	The **Comment** field can be used to send a note to data management regarding this form. **Patient T18 Page 1 (REG for Baseline)** Visit Date [ ] ··· Blank ☐ Comment [ ] To enter a comment, click in the **Comment** field and type your message.	
	Practice entering a date into the PDF-based eCRF by entering the Visit date as indicated on the Registration Form found in Training Case #1.	
Navigating the eCRF	Keyboard shortcuts can also be used to move through the fields found on the eCRF. To move to the next field, press **<Tab>** or **<Enter>**. Press **<Shift+Tab>** to move back a field. Press **<Page Down>** to advance to the next field after a repeating group.	
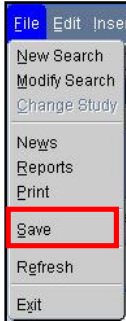
Action	Steps	Notes
	If the field displays an **ellipsis (…)** button**,** click on the button to view a List of Values (Discrete Value Group) available for that field.	
	To select from a List of Values, use the **Up** or **Down arrow** keys to highlight the value you wish to enter and click the **OK** button. You can also double-click on the value to select from the list. **Note:** Using the Discrete Value Group to select field values can save considerable data entry time.	
Entering Data for Repeating Record Groups	eCRFs often use repeating record groups to control the data entry process. A repeating record group is a set of questions with predetermined outcomes.	
	In this example, the predetermined responses are Normal, Abnormal or Not Examined.	
	Entering data into a repeating record group such as this can be done in three ways: • Type your response (in the case of simple responses such as Yes/No you only need to type the first letter. In this case, users must enter at least the first three letters of the chosen response.)	
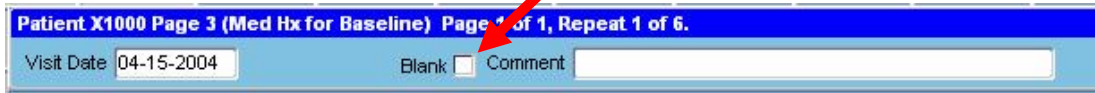
Action	Steps	Notes
	• Click in the response field to display the ellipsis button. After clicking the ellipsis, a discrete value list will display showing the available options for the field. Click on the data value in the list to select it. • After completing the first field, move to the next field by pressing the down arrow. Press F3 to enter the same value entered in the field above.	
Navigating through a Repeating Record Group	Press <Tab> or <Enter> to move to the next field.	
	After completing data entry in the Repeating Record Group, press **<Page Down>** to advance to the next question or scroll down and click in the next field.	
	NOTE: At the end of the repeating groups, if you press <Tab> or <Enter> a warning message will display. Click on the OK button. The system will automatically add a new blank row to the repeating record group. To eliminate the blank row and continue data entry, select Delete Row from the CRF pull-down menu.	

Action	Steps	Notes
	To continue with data entry, press <Page Down> or click in the next field.	
Correcting Univariate Discrepancies	With OC-RDC, the user can correct data entry errors before they are saved. As you enter data, the system automatically conducts a *univariate validation* check on each field that you enter. A **Univariate Validation Failure** box with a discrepancy message will appear on your screen when: • An invalid data value is entered • A value that is outside the expected range is entered • Required data fields are left blank.	

Types of univariate discrepancies include:

Mandatory	A required data was left blank.
Field Length	The text or value exceeds the number of spaces that allowed.
Precision	A number was entered with more decimal places than required for the field .
Data Type	The data type is not appropriate for the field (e.g., numeric data entered into a field calling for text, dates entered into a field calling for numeric data)
Upper and Lower Bounds	The data entered falls outside of the expected value range.
DVG	The value entered is not in the List of Values (Discrete Value Group).
DVG Subset	The value entered is in the base

Action	Steps		Notes
	Partial Date	The full date was not entered.	
Correcting Univariate Discrepancies While Performing Data Entry	**STEP 1**: When a Univariate Validation Failure dialog box appears, first review the type of failure and the message that is provided.		
	In this example, the temperature value supplied exceeds the expected number of digits. This creates a univariate discrepancy.		
	NOTE: Check the CRF or other source documentation to verify that the data entered into the eCRF matches the written document. If incorrect data was entered into the eCRF or if a mandatory field was skipped, the error can be corrected before the eCRF is saved.		
	STEP 2: If you can correct the failure immediately (e.g., you mistyped the response), click the **Cancel** button to return to the data entry screen.		
	STEP 3: Enter the correct value into the field and continue with data entry.		

Action	Steps	Notes
	STEP 4: If the data entered into the eCRF is the actual value recorded on source documentation, or if you do not have the information for a required field, enter a brief explanation in the "Comments" field and click the **OK** button. The comment becomes part of the study's audit trail. 	
	After the univariate discrepancy has been saved, the system will shade discrepant fields in *yellow*. 	
	When data entry for an eCRF is complete, but there is at least one discrepancy in the eCRF, the OC-RDC system displays the form icon in *red*. 	

Action	Steps	Notes
Saving eCRF Data	After you have completed data entry for the eCRF, you should save the data before continuing. To save the data: • Click on the File menu, then select Save on the pull-down menu; or • Click the Save icon on the toolbar ; • Press the <F10) key; or • If your study has been set to the automatically progress to the next CRF, press <TAB> or<ENTER> after the last entry.	
	The system saves the entries to the database and a "completed CRF" icon appears in that cell, (Assuming the eCRF does not contain any discrepancies.)	
	NOTE: Saving data using the <F10> key, the Save icon or the File-Save menu option works differently depending upon whether or not your OC-RDC is configured to automatically progress to the next eCRF.	
	You should only use these Save options if you know your study's data entry setup. Some studies are set up so that when you SAVE the data, the system assumes you have completed the form. In this case, OC-RDC closes the data entry window and automatically advances to the next form and opens a new data entry window. Once this happens, any additional data for that saved eCRF form must be entered as a correction.	

Action	Steps	Notes
	If your study requires you to manually close the data entry window and open the next one (automatic form progression is turned off), you will be able to SAVE data and continue the data entry process for the eCRF.	
	If your study is set to automatically advance to the next eCRF when you complete one eCRF, the system will automatically open the next eCRF as a blank form. In this situation, you may either enter data for the new form, or you can bypass the new form by choosing one of three options: • Finish the data entry session by clicking the **Cancel** button. • Skip this page by clicking the Next Page icon on the toolbar • Mark the page as blank by clicking in the Blank box	
	Patient X1000 Page 3 (Med Hx for Baseline) Page 1 of 1, Repeat 1 of 6. Visit Date 04-15-2004 Blank ☐ Comment	
	NOTE: You will also be prompted with a confirmation window when you select the Blank checkbox in the CRF header.	

Action	Steps	Notes
Explicit vs. Implicit Saves	**Explicit Saves** Explicit saves require a user response before any pending data changes are saved. In these situations the OC-RDC system will display a confirmation window requiring the user to confirm that the data changes are to be saved.	
	Explicit saves are performed when the user: • Clicks on the "X" in the upper right-hand corner of the Data Entry window to close the window; • Clicks on the "X" in the upper right-hand corner of the Main Application window; • Clicks on the Exit button on the Toolbar. **NOTE:** When the confirmation dialog box displays, you must answer "Yes", or your data will be lost!	
	Implicit Saves The OC-RDC system automatically saves pending changes to eCRF data in the following situations: • After initial date entry – press the <Enter> or <Tab> key when the focus is in the last response field in the last CRF section (all required header data must be entered). • After data update – click on the Save button in the Audit Information window. • When opening the Search window, in either New or Modify Search mode. • When changes are made to the page grouping tab.	

Action	Steps	Notes
	The OC-RDC system also saves pending data changes automatically in the following situations: • When a new patient is inserted. • When the validate menu is used to validate the page, patient, site of study. • When an eCRF is approved or verified. • When the user clicks the Show/Hide Unplanned Pages button on the spreadsheet. • When the user clicks another eCRF icon. • When the user clicks another eCRF section tab. • When the user selects another patient from the List of Current Patients. In these situations, the OC-RDC system will not display a confirmation window. The pending changes will be automatically saved.	

Exercise 5-1:   Input Data into an eCRF

Scenario: You have been tasked with data entry for a new CRF.

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Insert a new patient into the RDC study database.	
	Enter the data for this patient from the baseline CRF into the RDC study spreadsheet.	
	▪ Enter Information from the Registration Form	
	▪ Enter Information from the Randomization Form	
	▪ Enter Information from the Baseline Symptoms Form	
	Enter the data for this patient from the Visit 1 CRF into the RDC study spreadsheet.	
	▪ Enter Information from the Physical Exam Form	
	▪ Enter Information from the Clinical Laboratory Data Hematology Form	
	Enter the data for this patient from Visit 2 into the RDC study spreadsheet.	
	▪ Enter Information from the Compliance Form	
	Enter the data for this patient from Concomitant Medications into the RDC study spreadsheet.	
	Note: Do not enter data from the Clinical Laboratory Data – Urine CRF for Visit 1 or any CRFs for Visit 1.1 at this time!	
	When you are finished with the data entry of all eCRFs, wait for further instructions from your instructor.	

Version 09/27/2005

Summary of Lesson 5

Basic Data Entry in OC-RDC is accomplished using the RDC spreadsheet and the Data Entry screen. Each CRF has a unique data screen designed to collect all of the essential data found on the paper Case Report Form.
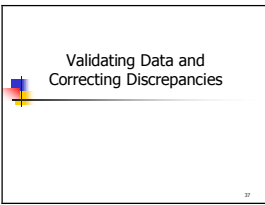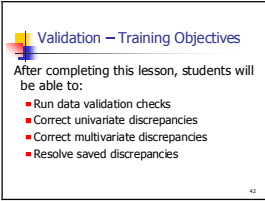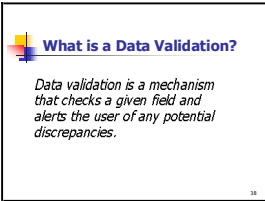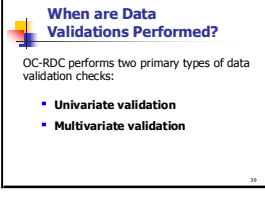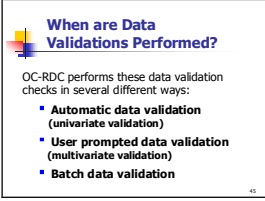
Data Entry begins when a new patient is added to the study database. Data Entry continues as the user completes the required header information in the eCRF. After the header information has been entered, the remaining data field can be completed and saved to the study database.
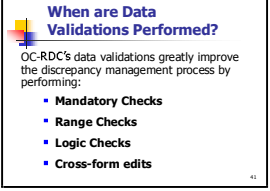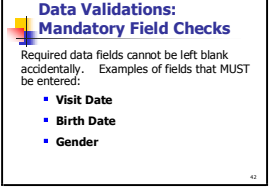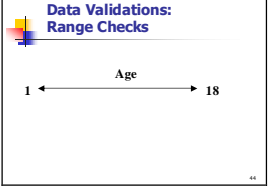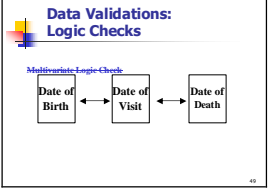
When a user clicks on an existing eCRF in the RDC spreadsheet, the Data Entry screen for that eCRF opens automatically. Clicking on a blank cell in the RDC spreadsheet automatically creates a new eCRF and opens the Data Entry screen for that eCRF.
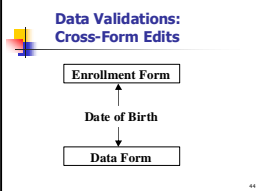
Review

1. Describe three ways to enter yesterday's date for a patient visit.

2. List three ways to add a new patient to the study database.

3. Data is always saved when exiting the OC-RDC application - True or False?

4. After entering data into a Repeating Records Group, how do you move to the next field?

5. If your OC-RDC system is set to automatically progress to the next form, how can you skip data entry for a form?
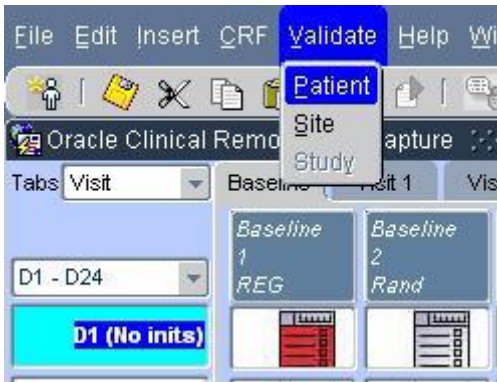
Validating Data and Correcting Discrepancies
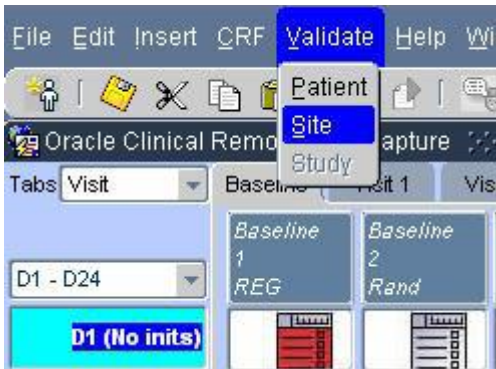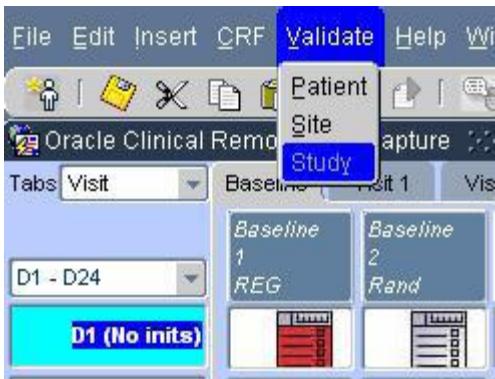
Introduction	A discrepancy is a data point that falls outside of allowable parameters or conflicts with another datapoint. There are essentially two types of discrepancies identified and tracked in OC-RDC: univariate discrepancies and multivariate discrepancies.
	A univariate discrepancy is any single datapoint that does not meet the specified data validation parameters for that field. Examples of univariate discrepancies include:
	▪ Temperature measurement above or below the expected range
	▪ Systolic blood pressure reading above or below the expected range
	▪ Data that exceeds the anticipated field length (i.e. entering 8 characters into a field limited to 6 characters or less)
	▪ Incorrect data type (i.e. text entered into a field limited to numeric values)
	▪ Mandatory fields that are left blank
	A multivariate discrepancy is generated when datapoints conflicts with one another. The conflicting datapoints may be found on a single CRF or the discrepant datapoints may be found on separate CRFs. In either case a multivariate discrepancy will be generated by the OC-RDC system. Examples of multivariate discrepancies include:
	▪ Pregnancy questions answered for a patient identified as Male
	▪ Number of cigarettes smoked per week specified for a patient indicated as a non-smoker
	▪ Hospitalization form completed for a patient indicated as not having been hospitalized since the last visit
	In addition to these system-generated discrepancies, users can enter manual discrepancies to communicate information about a response value or about the about the condition of the source data.
	OC-RDC incorporates multiple levels of data validation to help ensure that the data entered is appropriate, within expected parameters and at the specified level of precision. OC-RDC checks data and alerts the user of any discrepancies.
	OC-RDC performs these data validation checks in several different ways:
	– Automatic data validation is performed as data is entered into an eCRF (univariate validation.)
	– User prompted data validation is performed when the user presses the "Validation" key (multivariate validation)
	– Batch data validation is performed after the data entry process has been completed. This type of data validation is typically performed by data managers at Westat
Lesson Objectives	After completing this lesson, learners will be able to:
	– Correct univariate discrepancies
	– Run data validation checks
	– Correct multivariate discrepancies
	– Resolve saved discrepancies
New Terms	No new terms are introduced in this lesson.
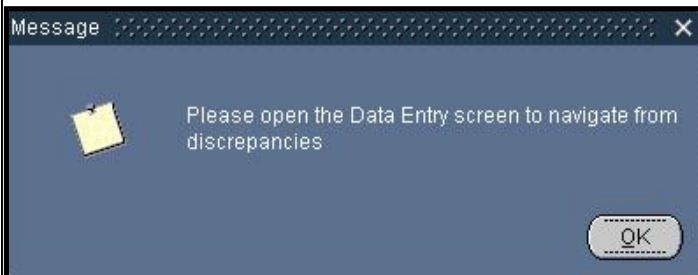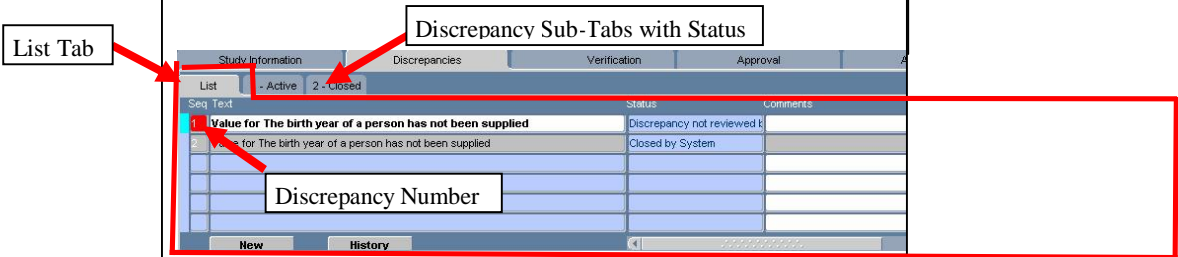
Screen Visual		Notes
Validating Data and Correcting Discrepancies	Correcting Discrepancies	
Validation – Training Objectives After completing this lesson, students will be able to: ■ Run data validation checks ■ Correct univariate discrepancies ■ Correct multivariate discrepancies ■ Resolve saved discrepancies	After completing this lesson, learners will be able to: – Run data validation checks – Correct univariate discrepancies – Correct multivariate discrepancies – Resolve saved discrepancies	
What is a Data Validation? *Data validation is a mechanism that checks a given field and alerts the user of any potential discrepancies.*	OC-RDC incorporates multiple levels of data validation to help ensure that the data entered is appropriate, within expected parameters and at the specified level of precision. OC-RDC checks data and alerts the user of any discrepancies.	
When are Data Validations Performed? OC-RDC performs two primary types of data validation checks: ▪ **Univariate validation** ▪ **Multivariate validation**	OC-RDC performs two primary types of data validation checks: – Univariate validation – an edit check of single data field to determine if the data entered is allowable (e.g., is the data within the expected range, the correct data type, suitably precise, etc.) – Multivariate validation – an edit check that compares two or more data fields for consistency	
When are Data Validations Performed? OC-RDC performs these data validation checks in several different ways: ▪ **Automatic data validation (univariate validation)** ▪ **User prompted data validation (multivariate validation)** ▪ **Batch data validation**	OC-RDC performs these data validation checks in several different ways: – Automatic data validation is performed as data is entered into an eCRF (univariate validation.) – User prompted data validation is performed when the user presses the "Validation" key (multivariate validation) – Batch data validation is performed after the data	
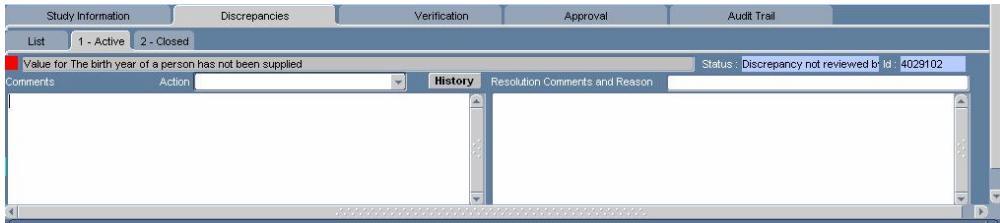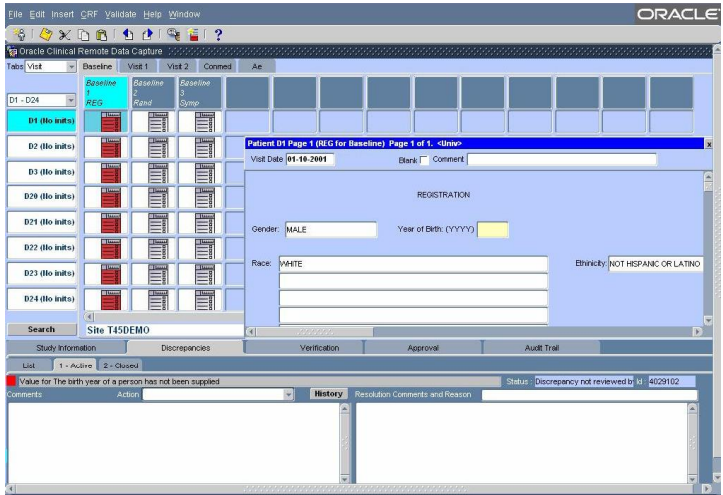
Screen Visual		Notes
	entry process has been completed. This type of data validation is typically performed by data managers at Westat.	
When are Data Validations Performed? OC-RDC's data validations greatly improve the discrepancy management process by performing: ▪ Mandatory Checks ▪ Range Checks ▪ Logic Checks ▪ Cross-form edits	OC-RDC's data validations greatly improve the discrepancy management process by performing: • Mandatory Checks • Range Checks • Logic Checks • Cross-form edits	
Data Validations: Mandatory Field Checks Required data fields cannot be left blank accidentally. Examples of fields that MUST be entered: ▪ Visit Date ▪ Birth Date ▪ Gender	Mandatory Checks − required data fields cannot be left blank accidentally. Examples of fields that MUST be entered: – Visit Date – Birth Date – Gender Since mandatory checks apply to individual fields, this is an example of a univariate validation.	
Data Validations: Range Checks 1 ◄——— Age ———► 18	Range Checks − data is checked to ensure that it falls within the expected range of values Like mandatory checks, range checks evaluate the data entered into a single data field, so this type of check is also a univariate validation.	
Data Validations: Logic Checks Multivariate Logic Check Date of Birth ◄► Date of Visit ◄► Date of Death	Logic Checks − data is checked to ensure that it is of the appropriate type for the field (e.g., a date is entered into the visit date fields, numbers are entered into temperature fields, etc.) This is an example of a univariate logic check − it checks a single field. Logic checks can also be multivariate validations as is the case when OC-RDC checks to validate that the visit date falls between the patient's birth date and death date.	
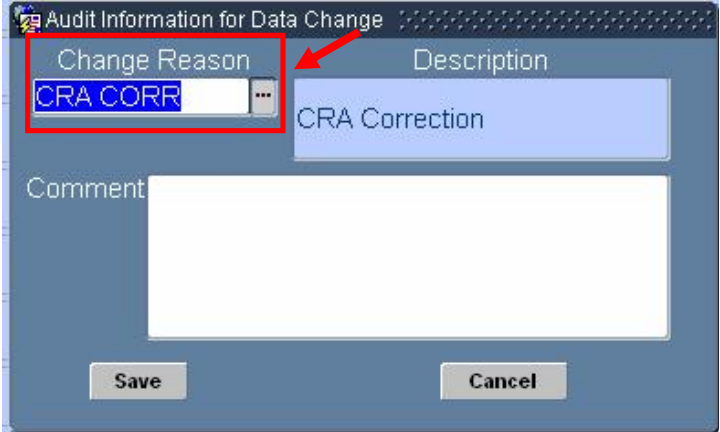
Screen Visual		Notes
Data Validations: Cross-Form Edits Enrollment Form Date of Birth Data Form	Cross-form edits – values entered into fields on one eCRF are checked to ensure that they are consistent with data entered into fields on other, related eCRFs. Cross-form edits are multivariate validations.	
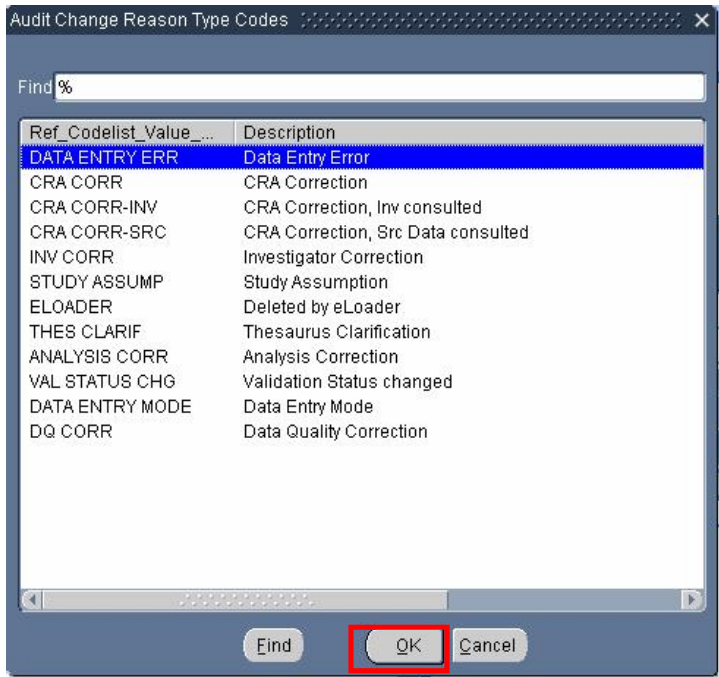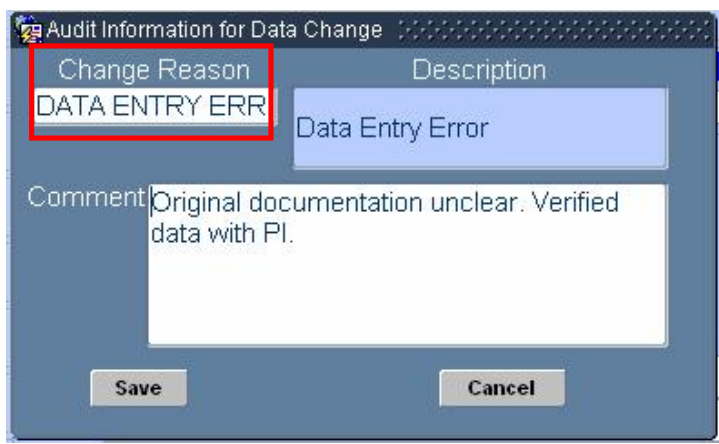
Action	Steps	Notes
Validating Data	After the data has been entered and saved for an eCRF, validation checks on the data must be run to identify any discrepancies. OC-RDC provides three levels of data validation: • **Patient validation** validates all eCRF forms for a specific patient (one row in the spreadsheet). • **Site validation** validates all forms for all patients at the selected site (all rows and all columns in the site spreadsheet). • **Study validation** validates all sites in the entire study. Site validation can only be executed by data managers at Westat.	
	To validate data for a single patient, click on the patient ID that you want to check. Then, go to the validate menu and select Patient from the drop-down list. You can also use the short-cut keys to access the patient validation by pressing ALT-v and then press P.	
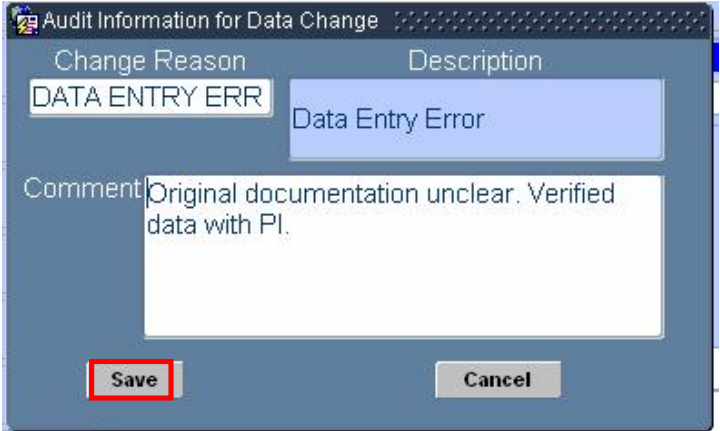
Action	Steps	Notes
	To validate data for an entire site, go to the validate menu and select Site from the drop-down list. You can also use the short-cut keys to access the site validation by pressing ALT-v and then press s.	
	If you have permission to run study validation checks, you can run the study validation check by selecting the Study option from the drop-down list on the validate menu. You can also use the short-cut keys to access the study validation by pressing ALT-v and then press y.	
	If the OC-RDC system finds a discrepancy on any eCRF, the icon for that eCRF will be displayed in *red*.	
Resolving Saved Data Discrepancies	Every univariate and multivariate discrepancy must be resolved before your work on an eCRF is considered complete.	

Action	Steps	Notes
	STEP 1: To *correct* a saved discrepancy, click the eCRF containing the discrepancy (indicated by a red icon).	
	WARNING: Be sure that the data entry window for the eCRF is open before you try to correct any discrepancy. If the data entry window is not open, OC-RDC will display the following message:	
	STEP 2: Click on the *Discrepancies* tab to display the discrepancy information for the selected eCRF. The "List" tab displays information about all the discrepancies on the eCRF. Colored blocks on the left edge of each row indicate the discrepancy number (they are shaded in red, yellow, or grey). For each discrepancy there is also a numbered sub-tab that lists the discrepancy status (e.g, "Active", "Closed", "Other"). 	

Action	Steps	Notes
	STEP 3: Click the **numbered sub-tab** for the discrepancy needing resolution. The system will display the variables and values causing the discrepancy.	
	STEP 4: Select "Go to data field" from the Action pull-down menu. Your cursor will automatically move to the data field containing the discrepancy. 	
	STEP 5: Enter the correct information as verified by the source documentation. 	
	STEP 6: Click the **Save** button.	

Action	Steps	Notes
	STEP 7: The system displays the "Audit Information" window. A default value will automatically be displayed in the "Change Reason" box. To change the reason for the data correction, click on the ellipsis button (…) to display the "Change Reason" list box	
	STEP 8: Select the appropriate reason for the data change from the Audit Change Reason Type Codes list and click the OK button.	

Action	Steps	Notes
	STEP 9: The new change reason will be displayed in the Audit Information dialog box. Enter any comments explaining the data change into the Comment field, if required by your study. This field is not required by OC-RDC, but your study might require you to further explain the reason for a change. 	
	STEP 10: Once you have completed entering the	

Action	Steps	Notes
	necessary audit information, click the Save button to record your change reason and comments.	
	The system closes the "Audit Information" window, returns to the Discrepancies tab.	
	STEP 11: Repeat this procedure for each discrepancy you wish to correct.	
	STEP 12: After the discrepancies have been corrected, the data must be validated again. If your corrections clear the discrepancies and there are no other discrepancies for the page: • The eCRF icon will change from red to white. • The individual discrepancy sub-tabs will indicate that the discrepancy is "Closed" If a discrepancy remains or a new one is identified, the eCRF icon remains red and the discrepancies will remain "Active."	
Forwarding Discrepancies	There will be times when you cannot resolve a discrepancy. For example, if the discrepancy is the result of a value that is actually reported on the CRF, you might need to request an override of the discrepancy. Another example requiring a data	

Action	Steps	Notes
	override is a data item that cannot be obtained from the source documentation even though it is considered mandatory by the OC-RDC system.	
	STEP 1: To assign the discrepancy to a data manager at Westat, click the red icon for the eCRF.	
	STEP 2: Click the Discrepancies tab.	
	STEP 3: Click the numbered sub-tab for the discrepancy you wish to forward.	
	STEP 4: Click on the Action drop down arrow. Select "Send to Data Mgt" from the list box.	

Action	Steps	Notes
	STEP 5: Enter a comment to describe the override reason. 	
	STEP 6: Click the **Save** button. 	
	After you select this action, the system changes the sub-tab status to "Other". The discrepancy is sent to Data Management for review. The eCRF icon changes to yellow.	
	NOTE: Depending on your assigned role in OC-RDC, you may have different options in Actions drop-down the list box.	

Exercise: Correcting a Univariate Discrepancy (Data Entry Error)

Scenario: *Correct univariate discrepancies*

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Confirm that the Registration eCRF in the Baseline visit indicates a discrepancy.	
	Open Registration eCRF for training case 1.	
	Review the indicated discrepancy.	
	Correct the discrepant data.	
	Enter a note indicating that the source documentation was checked and the data was corrected on the eCRF.	
	Did the icon for this eCRF change?	
	What color is the icon now?	
	What does this indicate about the data on the eCRF?	
	Confirm that the Physical Exam eCRF for visit 1 indicates at least one discrepancy.	
	Open Physical Exam eCRF for visit 1.	
	Review the indicated discrepancies.	
	Which values are indicated as being discrepant?	
	Why is each indicated as discrepant?	
	Use the discrepancy task tab to edit the value for Pulse to fit within the required parameters.	

Exercise: Sending a Univariate Discrepancy to the Data Manager

Scenario: *Sending Univatiate Discrepanies to Data Manager*

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Confirm that the Physical Exam eCRF for visit 1 still indicates at least one discrepancy.	
	Review the indicated discrepancies.	
	Which values are still indicated as being discrepant?	
	Why is each indicated as discrepant?	
	Assume that the value 70 for Systolic blood pressure is accurate.	
	Choose the discrepancy sub-tab for Systolic blood pressure in the discrepancy task tab.	
	Choose the action "Send to Data Management"	
	Enter a note indicating that the source documentation was checked and that the data is accurate.	
	Assume that the value 120 for Diastolic blood pressure is accurate.	
	Choose the discrepancy sub-tab for Diastolic blood pressure in the discrepancy task tab.	
	Choose the action "Send to Data Management"	
	Enter a note indicating that the source documentation was checked and that the data is	

Step	Instructions/Screen Visual	Notes
	accurate.	
	Continue with discrepancy management for all remaining univariate discrepancies.	

Exercise: Validating Patient Data

Scenario: *You have been tasked with validating the patient data recorded in the OC-RDC database.*

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Validate the patient data.	
	Were any new discrepancies identified?	
	How can you tell?	
	Which eCRFs for this patient contain multivariate discrepancies?	
	What data is discrepant?	
	Why were these discrepancies not displayed prior to validating the data?	

Exercise: Correcting a Multivariate Discrepancy

Scenario: *Correcting a Multivariate Discrepancy*

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Identify the multivariate discrepancies on Physical Exam eCRF for Visit 1.	
	It is determined that the units for height was entered incorrectly. Go to the Discrepancy task tab.	
	Choose the sub-tab for the discrepancy for Height values.	
	Choose the variable for units (i.e. inches/ centimeters)	
	Use "Go to data field" from Action drop down.	
	Change units from centimeters to inches.	
	Continue to resolve all remaining multivariate discrepancies.	
	Once all multivariate discrepancies have been resolved, validate the patient!	

Summary

A discrepancy is datapoint that falls outside of allowable parameters or conflicts with another datapoint. There are essentially two types of discrepancies identified and tracked in OC-RDC: univariate discrepancies and multivariate discrepancies.

A univariate discrepancy is any single datapoint that does not meet the specified data validation parameters for that field.

A multivariate discrepancy is generated when datapoints conflicts with one another. The conflicting datapoints may be found on a single CRF or the discrepant datapoints may be found on separate CRFs. In either case a multivariate discrepancy will be generated by the OC-RDC system.

In addition to these system-generated discrepancies, users can enter manual discrepancies to communicate information about a response value or about the about the condition of the source data.

OC-RDC incorporates multiple levels of data validation to help ensure that the data entered is appropriate, within expected parameters and at the specified level of precision. OC-RDC checks data and alerts the user of any discrepancies.

OC-RDC performs these data validation checks in several different ways:

- Automatic data validation is performed as data is entered into an eCRF (univariate validation.)
- User prompted data validation is performed when the user presses the "Validation" key (multivariate validation)
- Batch data validation is performed after the data entry process has been completed. This type of data validation is typically performed by data managers at Westat
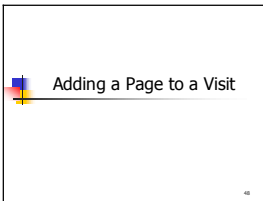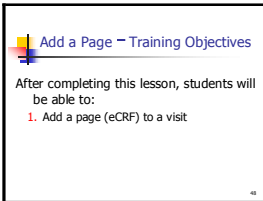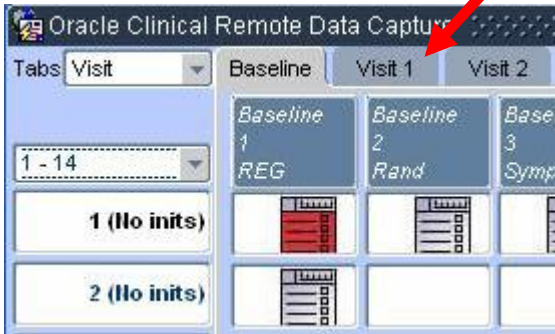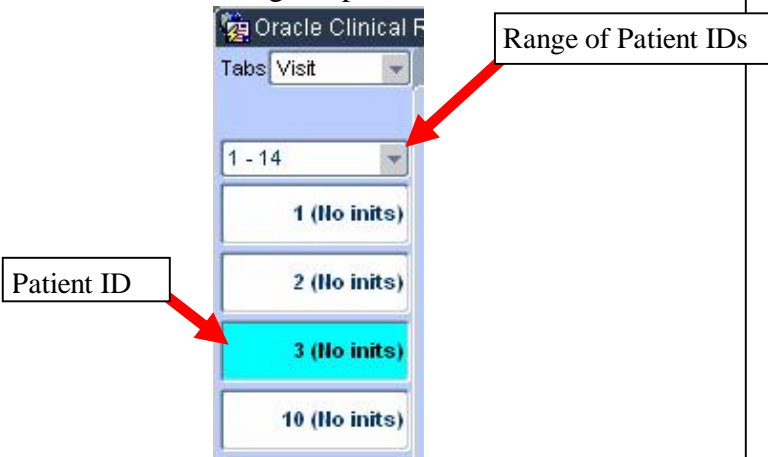
Review

1. How can you correct a univariate discrepancy while conducting initial data entry?

2. How would you correct a univariate discrepancy after the initial data entry information has been saved?

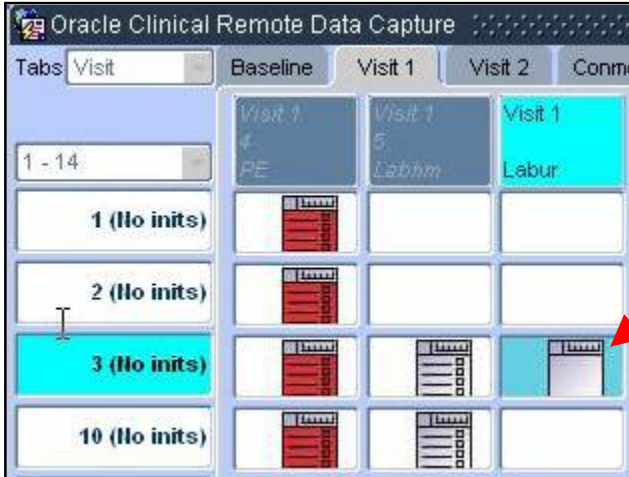3. How does OC-RDC identify eCRFs that contain discrepancies?

How would you notify your data manager that a discrepancy correction requires review?
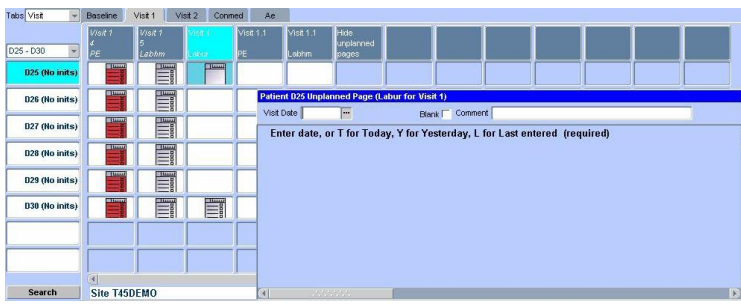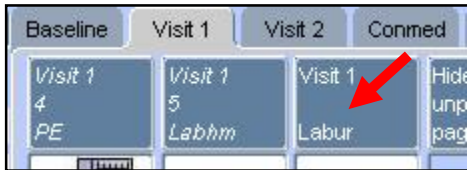
Adding a Page to a Visit

Introduction	It may be necessary to add an unplanned eCRF to the study database. This may be necessary when: • An unplanned exam or test is performed during a study visit • A form is collected only in special circumstances (e.g., an Death Report Form).
Lesson Objectives	After completing this lesson, learners will be able to: 1. Add a page (eCRF) to a visit.
New Terms	No new terms are introduced in this lesson.

Screen Visual		Notes
Adding a Page to a Visit		Estimated time to complete this lesson = 15 minutes
Add a Page – Training Objectives After completing this lesson, students will be able to: 1. Add a page (eCRF) to a visit	After completing this lesson, learners will be able to: • Add a page (eCRF) to a visit.	

Action	Steps	Notes
Insert an eCRF page	**STEP 1**: To add an eCRF to the study database, click on the appropriate Visit tab at the top of the spreadsheet. 	
	STEP 2: Click on the patient ID for which you want to add the new eCRF. If the patient ID is not among the eight IDs on the spreadsheet, change the patient view by clicking on the down-arrow in the Patients field and select the correct range of patients. 	
	If the ID is not on the spreadsheet, you may have to insert the new patient. Refer to the *Data Entry* lesson for instructions on how to insert a patient.	
	STEP 3: On the menu bar, click on Insert, CRF. 	
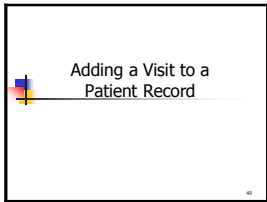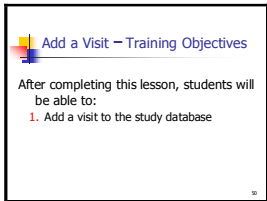
Action	Steps	Notes
	The system displays the "Add unplanned CRF" box for the selected patient and visit. Click the "**CRF**" arrow to display the pages available for addition.	
	STEP 4: Select the type of CRF page you want to add. You can only add pages that are predetermined for the study; i.e., you cannot make up your own page or add a page from some other source. **CRF list box**	
	STEP 5: A new unplanned CRF is added to the patient grid.	
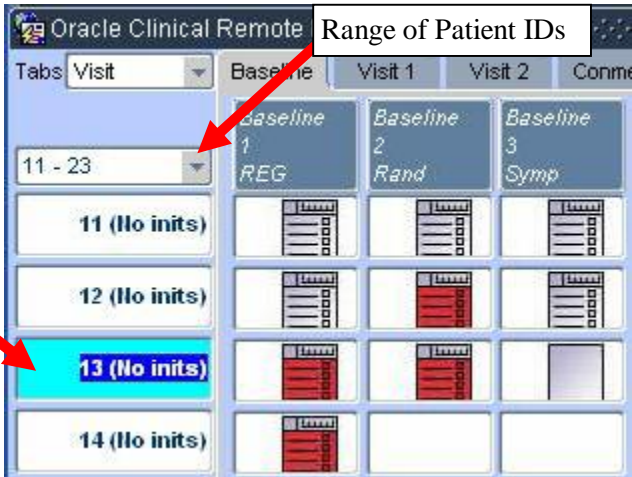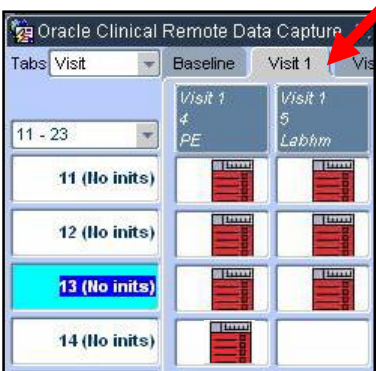
Action	Steps	Notes
	The data entry screen for the unplanned CRF opens automatically 	
	NOTE: Unplanned pages are not numbered on the Visit tab. 	Point out that if the column headers are examined very carefully, you can distinguish between planned and unplanned pages. Column headers for Planned pages are numbered and displayed in *italics*. Unplanned pages are not numbered and are displayed in a plain (non-italicized) type face.
	Practice adding an unplanned CRF by adding the results of the Clinical Laboratory Data Urine Form for Visit 1 on the patient you added in the previous lesson. Enter all data found on the paper CRF in Training Case #1. When you have completed the data entry, save and close the eCRF.	
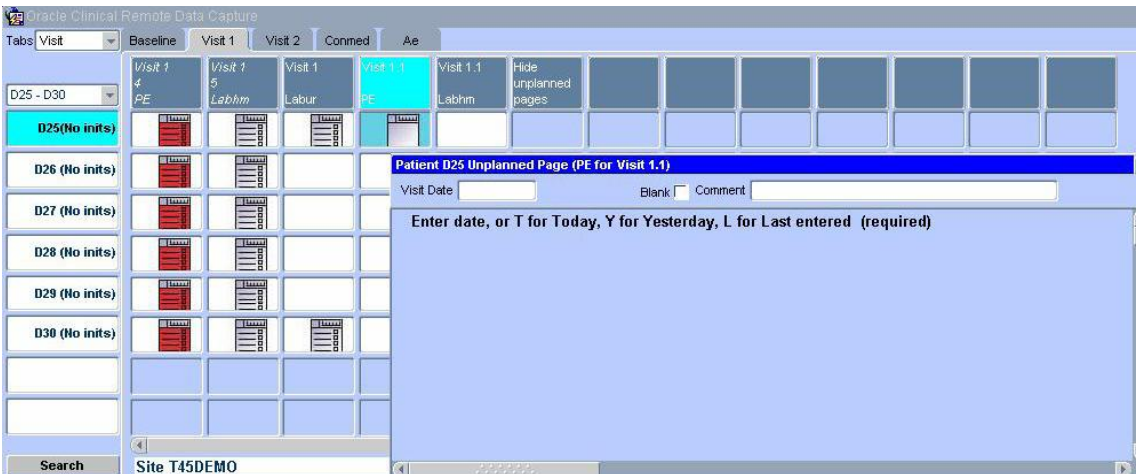
Summary	It may be necessary to add an unplanned eCRF to the study database. This may be necessary when:
	• An unplanned exam or test is performed during a study visit
	• A form is collected only in special circumstances (e.g., a Death Report Form).
	You can only add pages that are predetermined for the study; i.e., you cannot make up your own page or add a page from some other source.
	Unplanned pages are not numbered.
Review	1. Describe two situations which may require you to add an unplanned CRF page.
	2. What two variables must be selected in order to add a CRF page to the study database?
	3. What steps are necessary to add an eCRF page to the study database?
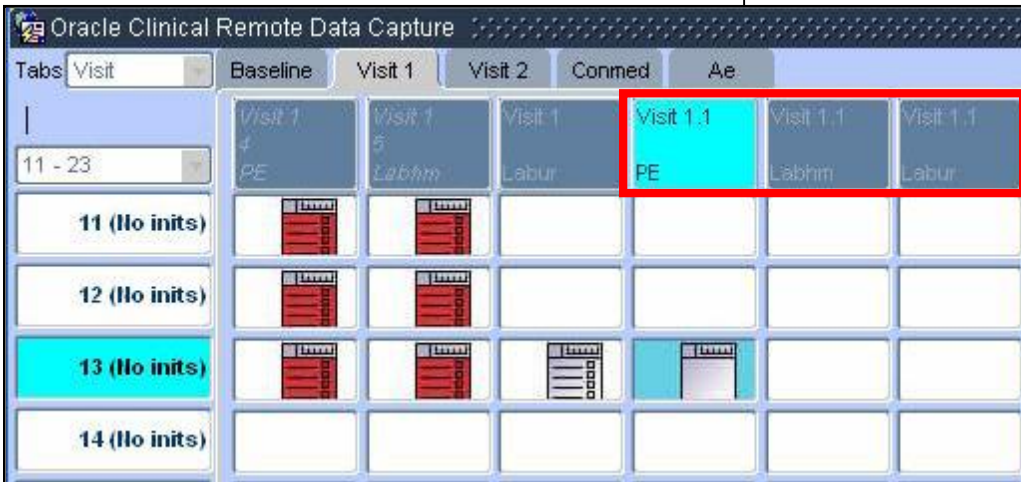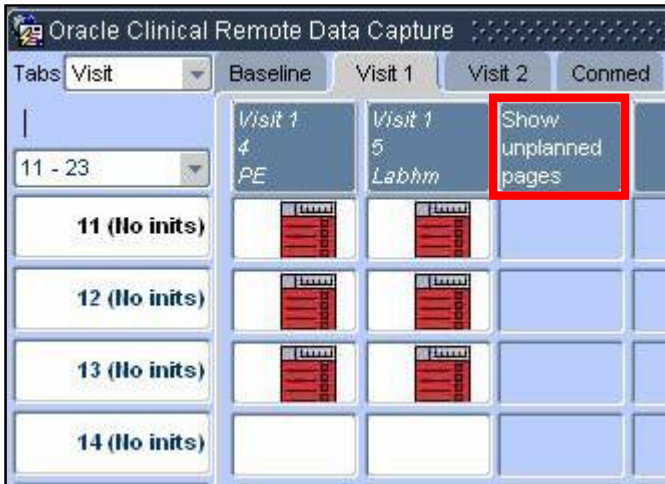
Adding a Visit to a Patient Record

Introduction	For some studies, it may be necessary to add your own visits to the study database. This might happen if an unscheduled visit occurs, or if patients are seen for a variable number of visits. For example, patients might receive followup visits every six months until the end of the study or time of death. Rather than plan for the maximum number of visits in the database, the study can be set up to allow additional followup visits to be added as they occur.
Lesson Objectives	After completing this lesson, learners will be able to: – Add a visit to the study database.
New Terms	No new terms are introduced in this lesson.

Screen Visual		Notes
Adding a Visit to a Patient Record		Estimated time to complete this Lesson = 15 minutes
Add a Visit – Training Objectives After completing this lesson, students will be able to: 1. Add a visit to the study database	After completing this lesson, learners will be able to: 1. Add an unplanned visit to the study database.	

Action	Steps	Notes
	STEP 1: Click on the patient ID for which you want to add the new visit. If the patient ID is not among the eight IDs on the spreadsheet, change the patient view by clicking on the down-arrow in the Patients field and select the correct range of patients. 	
	If the ID is not on the spreadsheet, you may have to insert the new patient. Refer to the *Data Entry* lesson for instructions on how to insert a patient.	
	STEP 2: Select the visit tab to where you want to add the new visit. The new visit will added immediately after the visit tab selected. For example if you want to add a visit between Visit 1 and Visit 2, you must be sure that the Visit 1 tab is selected. . 	

Action	Steps	Notes
	STEP 3: On the menu bar, click on Insert, Visit.	
	The system will remind you that you are adding an unplanned visit. To add a visit to a patient record, Click on OK.	
	The first eCRF in the new visit opens automatically for data entry.	
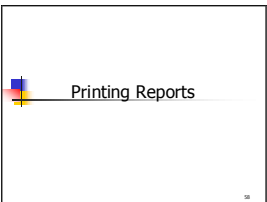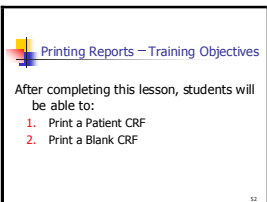
Action	Steps	Notes
	The OC-RDC system adds the eCRFs associated with the selected visit type to the patient grid.	
	OC-RDC's default setting does not display unplanned eCRFs or visits. However, if there are unplanned pages for the event tab, a header entitled *Show unplanned pages* will be displayed in the last column of the patient grid.	
	Click on this column header and the unplanned eCRFs or visits will be displayed.	
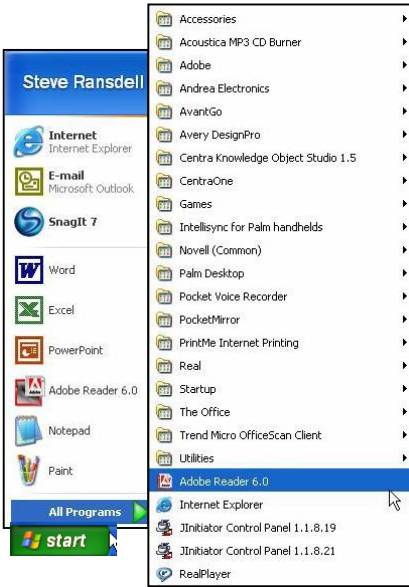
Action	Steps	Notes
	Unscheduled visits are displayed on the same Event tab as the previous <u>scheduled</u> visit. Unplanned visits can be hidden by clicking on the Hide unplanned pages header at the top of the last column. Event Tab Unplanned Visit Hide Unplanned Visit Header 	
	Note: Like unplanned pages, column headers for Planned visits displayed in *italics*. Unplanned visits are displayed in a plain (non-italicized) type face.	
	Practice adding an unplanned Visit by adding another Visit after Visit 1 but before Visit 2. Both a Physical Exam and a Hematology form will automatically be inserted. Enter all data found on the paper Physical Exam and Hematology CRFs for Visit 1.1 in Training Case #1. When you have completed the data entry, save and close the eCRF.	
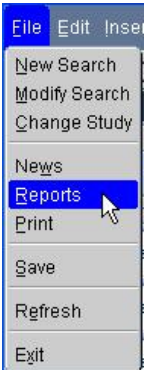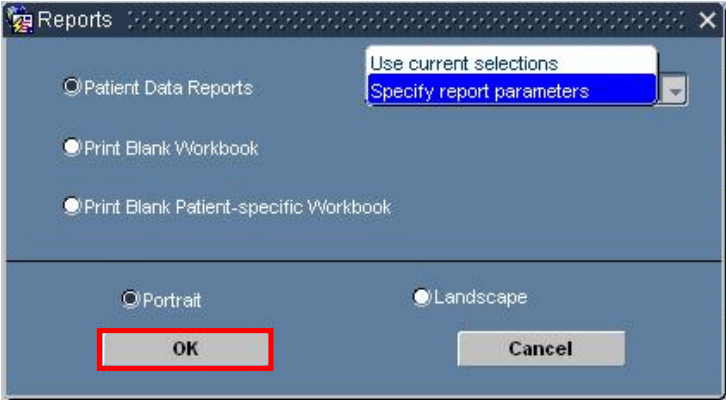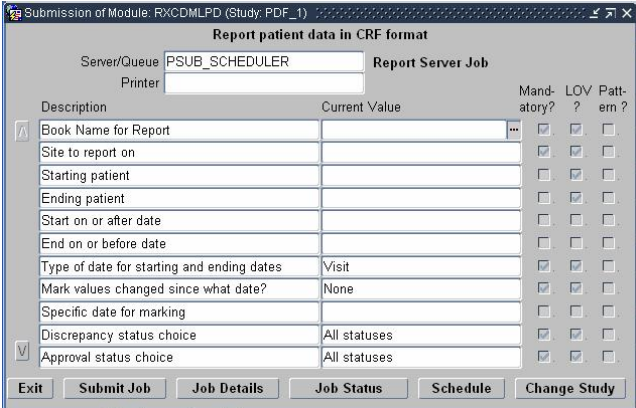
Summary	It may be necessary to add visits to the study database. Examples of unplanned visits include patients who are seen for a variable number of visits. For example, the study protocol may call for patient followup visits every six months until the end of the study or until time of death. In this situation, the database can be set up to allow additional followup visits to be added to the study database when they occur.
Review	1. Describe the steps necessary to add a new visit to the study database.
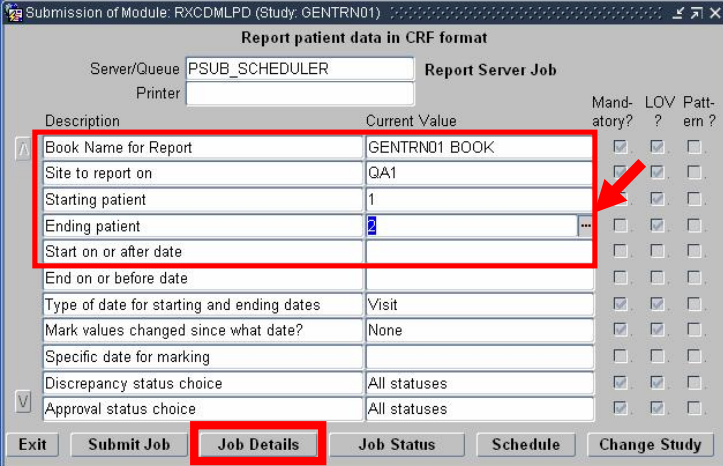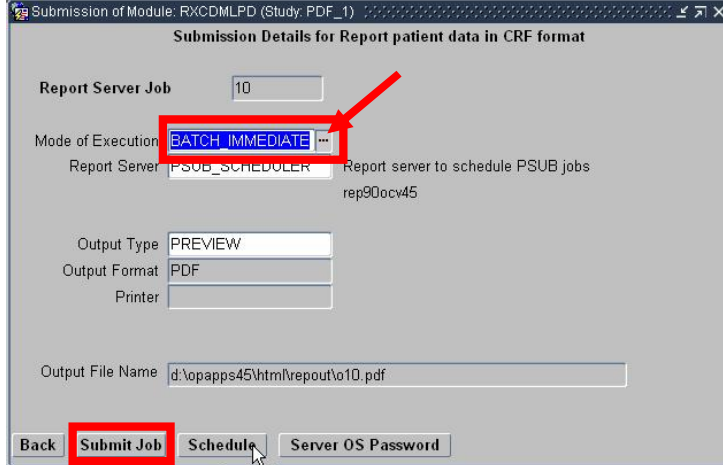
Printing Reports
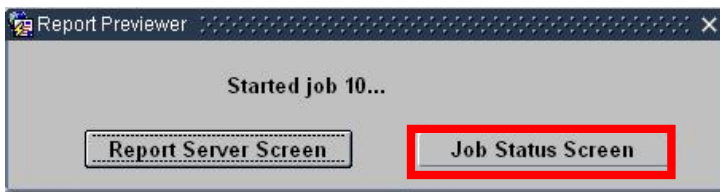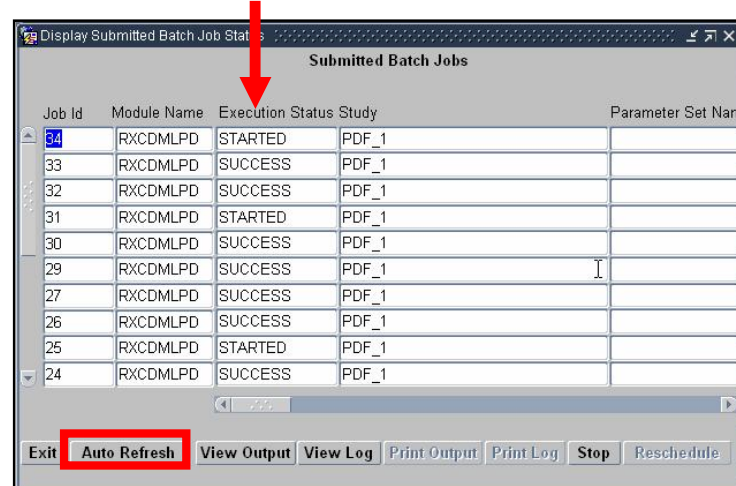
Introduction	RDC Reports allow the user to print patient data or blank CRFs. User-define search parameters are used to specify distinct subsets of patient data based on study factors such as: study, site, range of patient numbers, or dates. RDC 4.5 introduced new reporting functionality. There are essentially two types of reports:
	
	– Patient Data Report
	   • Current Search data can be used to generate the report, or
	   • Independent report criteria can be specified.
	– Blank CRF Report

Lesson Objectives	After completing this lesson, learners will be able to: 1. Print a Patient CRF 2. Print a Blank CRF.
New Terms	No new terms are introduced in this lesson.
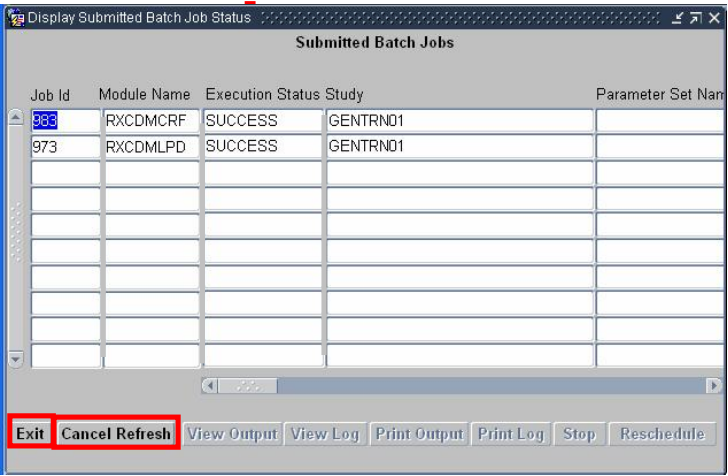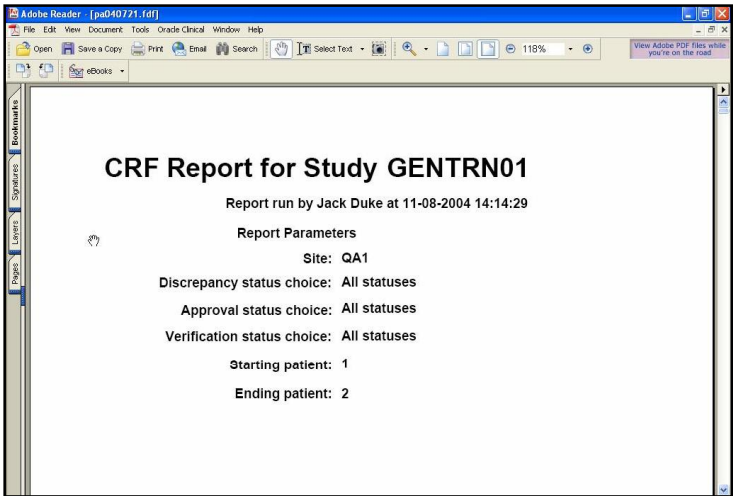
Screen Visual		Notes
Printing Reports		
Printing Reports – Training Objectives After completing this lesson, students will be able to: 1. Print a Patient CRF 2. Print a Blank CRF	After completing this lesson, learners will be able to: • Print a Patient CRF • Print a Blank CRF	
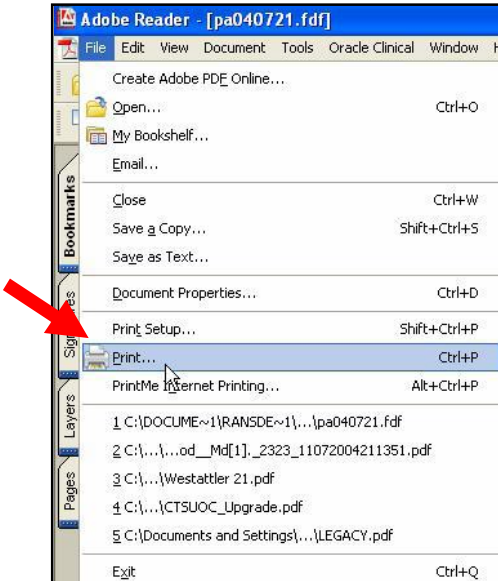
Activity	STEP	Notes
Launch Adobe Reader	Before printing completed CRFs from OC-RDC 4.5, Adobe Reader must be launched and minimized on your task bar. To do this:	
	STEP 1: Click on the **Start** button and then select **All Programs.** The program list will display. Select **Adobe Reader 6.0** from the Program List. **Note:** Depending on where Adobe Reader was installed on your computer, it may necessary to select the program folder or subfolders. 	
	STEP 2: The Adobe Reader welcome screen will display.	
	STEP 3: Once Adobe Reader fully loads, click on the minimize button in the upper right corner of the screen to minimize Adobe Reader onto the task bar. 	
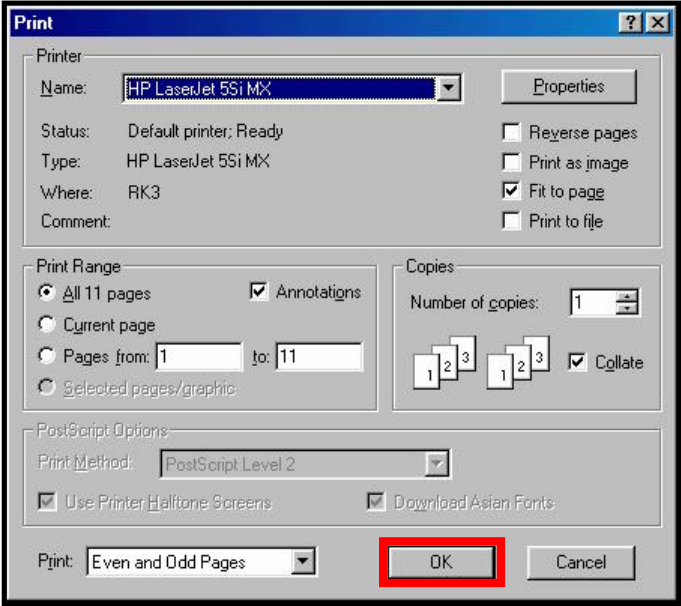
Activity	STEP	Notes
Printing Patient CRFs	To begin the print process: **STEP 1:** On the **File** menu select **Reports.**	
	STEP 2: Select **Patient Data Reports.** **STEP 3:** Click on the arrow and select **Specify report parameters** from the pull-down list**.**	
	STEP 4: Click on the **OK** button.	
	A dialog box will display.	
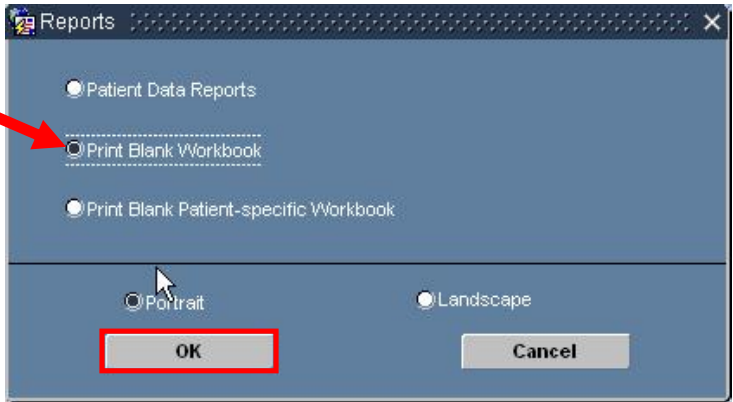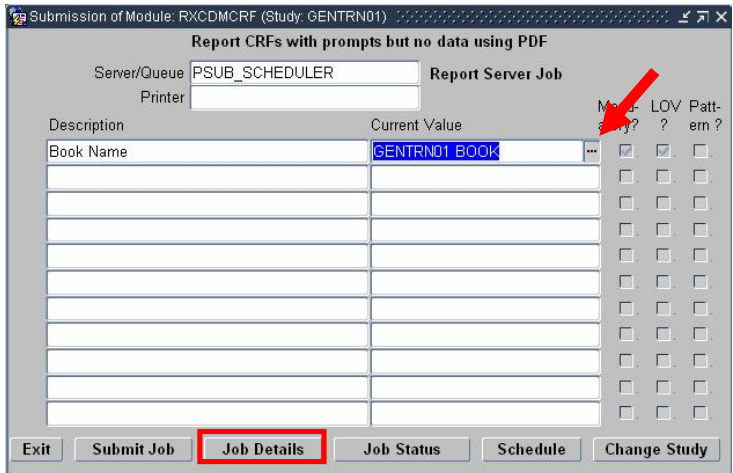
Activity	STEP	Notes
	STEP 5: Click on the ellipsis (…) in each field to enter the current value for the following parameters: • **Book Name for Report** • **Site to report on** • **Starting patient** • **Ending patient** 	
	STEP 6: Click on the **Job Details** button.	
	A dialog box displays listing the report submission details.	
	STEP 7: Click on the ellipsis (…) in the Mode of Execution field. Select **Batch Immediate** from the pull-down list. 	
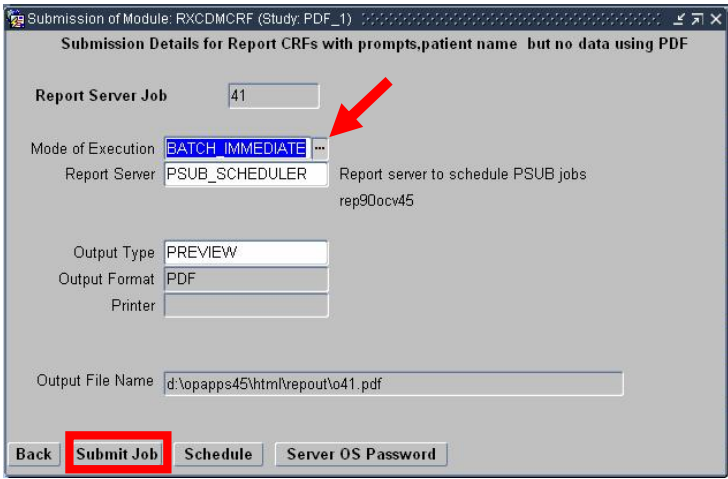
Activity	STEP	Notes
	STEP 8: Click the **Submit Job** button.	
	STEP 9: Click the **Job Status Screen** button.	
	STEP 10: The Submitted Batch Jobs window will display. The print job should be listed at the top of this list with the Execution Status indicating STARTED. Click on the **Auto Refresh** button.	

Activity	STEP	Notes
	STEP 11: Wait until the Execution Status for your print job indicates SUCCESS. 	
	STEP 12: Click on the **Cancel Refresh** button.	
	STEP 13: Click on the **Exit** button.	
	STEP 14: A blank Internet Explorer window will launch automatically.	
	STEP 15: Locate the Adobe Reader program previously minimized onto your task bar. Click on the task bar icon to maximize the Adobe Reader program. The CRF report is displayed in the Adobe Reader screen.	

Activity	STEP	Notes
	STEP 16: To print the CRF, select **Print** from the Adobe Reader **File** menu**.** 	
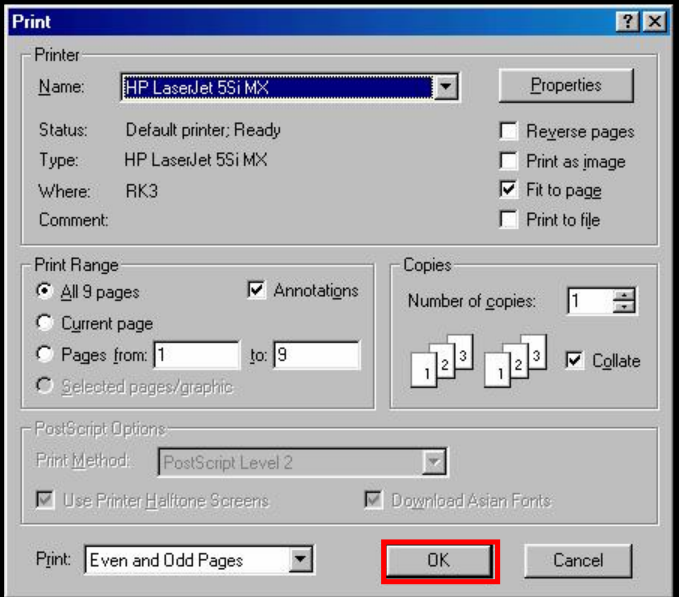
Activity	STEP	Notes
	STEP 17: Select the appropriate printer and specify any print parameters, then click the **OK** button.	
Printing Blank CRFs	OC-RDC also allows users to print blank CRFs. To print a blank CRF: **STEP 1:** On the **File** menu select **Reports.**	

Activity	STEP	Notes
	STEP 2: Select **Print Blank Workbook.**	
	STEP 3: Click the **OK** button.	
	STEP 4: Click on the ellipsis (…) in the Book Name field. Select desired book name from the pull-down list.	
	STEP 5: Click on the **Job Details** button.	

Activity	STEP	Notes
	A dialog box displays listing the report submission details. **Submission of Module: RXCDMCRF (Study: PDF_1)** Submission Details for Report CRFs with prompts,patient name but no data using PDF Report Server Job 41 Mode of Execution BATCH_IMMEDIATE Report Server PSUB_SCHEDULER Report server to schedule PSUB jobs rep90ocv45 Output Type PREVIEW Output Format PDF Printer Output File Name d:\opapps45\html\repout\o41.pdf Back Submit Job Schedule Server OS Password	
	STEP 6: Click on the ellipsis (…) in the Mode of Execution field. Select **Batch Immediate** from the pull-down list.	
	STEP 7: Click on the **Submit Job** button.	
	STEP 8: Click the **Job Status Screen** button. **Report Previewer** Started job 10... Report Server Screen Job Status Screen	

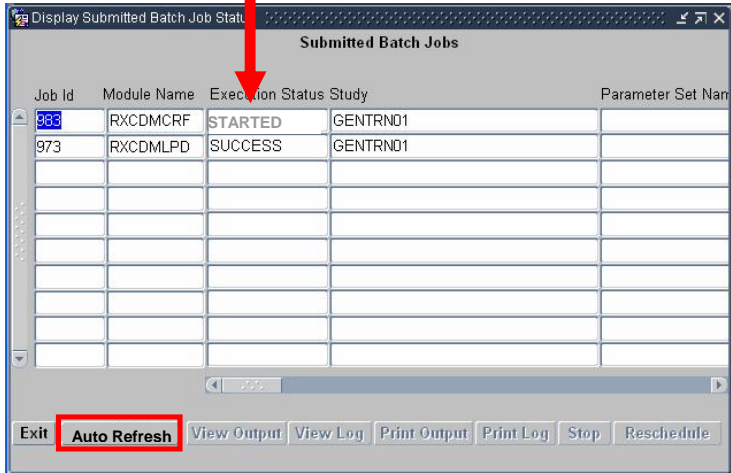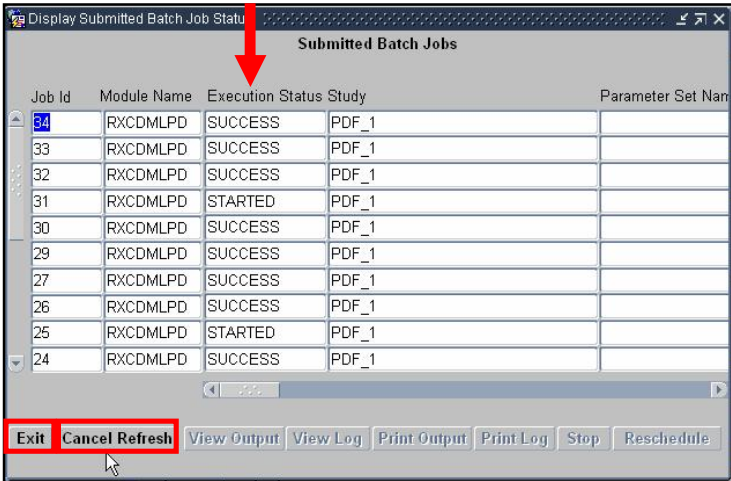| Activity	STEP	Notes
	STEP 9: The Submitted Batch Jobs window will display. The print job should be listed at the top of this list with the Execution Status indicating STARTED. Click on the **Auto Refresh** button. 	
	STEP 13: Wait until the Execution Status for your print job indicates SUCCESS. 	
	STEP 14: Click on the **Cancel Refresh** button.	
	STEP 15: Click on the **Exit** button.	
	STEP 16: A blank Internet Explorer window will launch automatically.	

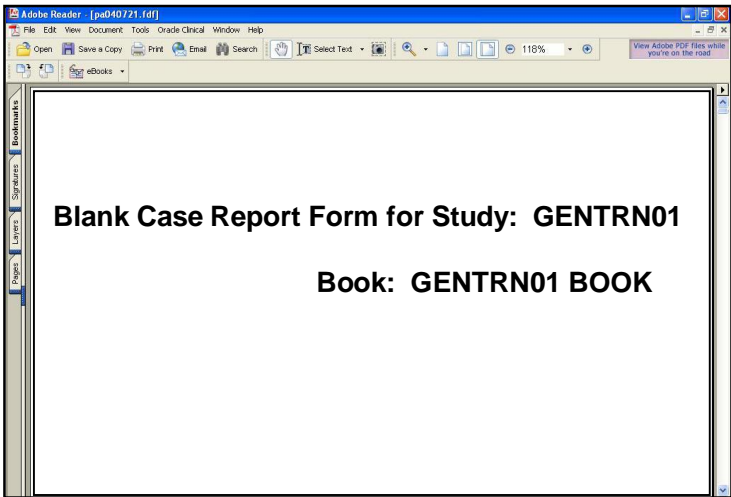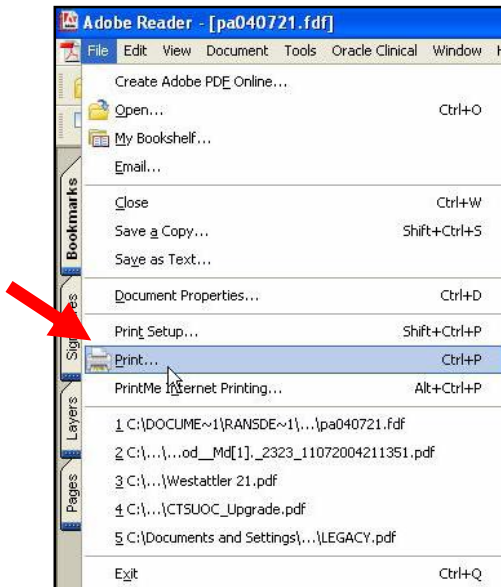| Activity	STEP	Notes
	STEP 17: Locate the Adobe Reader program previously minimized onto your task bar. Click on the task bar icon to maximize the Adobe Reader program. The CRF report is displayed in the Adobe Reader screen. **Blank Case Report Form for Study: GENTRN01** **Book: GENTRN01 BOOK**	
	STEP 18: To print the CRF, select **Print** from the **File** menu**.**	

Activity	STEP	Notes
	STEP 19: Select the appropriate printer and specify any print parameters, then click the OK button. 	

Summary	RDC Reports allow the user to print patient data or blank CRFs. User-define search parameters are used to specify distinct subsets of patient data based on study factors such as: study, site, range of patient numbers, or dates. RDC 4.5 introduced new reporting functionality. There are essentially two types of reports:
	    – Patient Data Report
	        • Current Search data can be used to generate the report, or
	        • Independent report criteria can be specified.
	    – Blank CRF Report

Review	1. Describe the process used to select and print patient CRFs. 2. Describe the process used to print Blank CRFs.

Hands On Exercise: Input Data into an eCRF

Scenario: You have been tasked with data entry for a new CRF.

Step	Instructions/Screen Visual	Notes
	Use the Sample CRFs found in Training Case 2, perform the following tasks:	
	Insert a new patient into the RDC study database as indicated on your OC-RDC Bookmark for Training Case #2.	
	Enter the data for this patient from the Baseline CRFs.	
	Enter all data exactly as indicated on the paper CRF. If univariate discrepancies are created, do not enter a comment. Click the OK button to close the warning dialog box.	
	Save and Close each form as data entry is completed.	
	▪ Enter Information from the Registration Form	
	▪ Enter Information from the Randomization Form	
	▪ Enter Information from the Baseline Symptoms Form	
	Enter the data for this patient from the Visit 1 CRFs.	
	▪ Enter Information from the Physical Exam Form	
	▪ Enter Information from the Laboratory - Hematology Form	
	Enter the data for this patient from the Visit 2 Compliance CRF into the RDC study spreadsheet.	
	Enter the data for this patient from the Concomitant Medications CRF into the RDC study spreadsheet.	
	When you are finished with data entry of all eCRFs, wait for further instructions from your instructor.	

Hands On Exercise: Add a Page to a Patient Visit

Scenario: You have been tasked with data entry of an unplanned CRF for a patient.

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 2 provided to you by your instructor, perform the following tasks:	
	Add an eCRF page for the unplanned urinalysis taken during Visit 1.	
	Using the Clinical Laboratory Data – Urine CRF found in your training materials enter all the data for this CRF.	
	Save and Close the eCRF	
	Add an eCRF Comments page for the Baseline Visit	
	Using the Comments CRF found in your training materials enter all the data for this CRF.	
	Save and Close the eCRF	
	Revalidate the patient.	

Add a Visit to a Patient Record

Scenario: *You have been tasked with data entry of an unplanned visit for a patient.*

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 2 provided to you by your instructor, perform the following tasks:	
	Add a new visit to the study database after Visit 1.	
	A new Physical Exam eCRF and Lab Hematology eCRF will automatically be inserted for this new visit.	
	Enter data found on the Physical Exam CRF for this visit.	
	Close the eCRF.	
	Enter data found on the Hematology CRF for this visit.	
	Close the eCRF.	

Hands On Exercise: Using the Search Window to View Discrepant Forms

Scenario: You have completed Data Entry for the patient identified in training case #2. Now you want to view only those CRFs for contain actionable or other discrepancies.

Note: Be sure to switch back to the Search Window display for this Exercise.

Step	Instructions/Screen Visual	Notes
	Launch the Search Window	
	Specify search parameters that will select only the patient inserted for training case #2	
	Specify a search for CRFs with actionable and other discrepancies only	
	How many forms are displayed on the RDC spreadsheet?	
	Which eCRFs are displayed?	
	What color are the icons representing those eCRFs?	

Correcting a Univariate Discrepancy or Sending to Data Management

Scenario: *Correcting univariate discrepancies when correctable, and sending others to data management*

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 2 provided to you by your instructor, perform the following tasks:	
	Find the first form that has 1 or more univariate discrepancies. It will be indicated by a red icon.	
	Open the form.	
	Review the indicated discrepancies with the discrepancy tab.	
	Open the numbered sub-tab for each discrepancy and review the discrepancy text.	
	Use the "go to" action wherever you can resolve the discrepancy.	
	Use the "Send to Data Management" action wherever you are unable to resolve the discrepancy.	
	Address each discrepancy. Use ellipsis for drop down menus where available. Correct the data if you can. If not, send the discrepancy to Data Management for resolution.	

Validating Patient Data

Scenario: *You have been tasked with validating the patient data recorded in the OC-RDC database.*

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 2 provided to you by your instructor, perform the following tasks:	
	Validate all patient data for this patient only.	
	Were any new discrepancies identified?	
	How can you tell?	
	Which eCRFs for this patient contain multivariate discrepancies?	
	Why were these discrepancies not displayed prior to validating the data?	

Correcting a Multivariate Discrepancy

Scenario: *resolve multivariate discrepancies*

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Identify the first CRF that contains a multivariate discrepancy. Note: the forms turned red after running the validation function.	
	Open the form.	
	Review the indicated discrepancies with the discrepancy tab.	
	Open the numbered sub-tab for each discrepancy and review the discrepancy text.	
	Use the "go to" action wherever you can resolve the discrepancy. Remember to indicate the desired variable to be changed.	
	Use the "Send to Data Management" action wherever you are unable to resolve the discrepancy.	
	Address each additional discrepancy. Use ellipsis for drop down menus where available. Correct the data if you can. If not, send the discrepancy to Data Management for resolution.	

Addressing Data Discrepancies

Scenario: *You have been tasked with reviewing the data for a Patient (Training Case 2).*

Note: If all discrepancies have been addressed (all eCRF icons are white or yellow) skip this exercise.

Step	Instructions/Screen Visual	Notes
	Using the Sample CRFs found in Training Case 2 provided to you by your instructor, perform the following tasks:	
	Review and address any remaining univariate discrepancies.	
	Validate the patient data.	
	Review and address any remaining multivariate discrepancies.	
	Validate the patient data again.	

Hands On Exercise: Using the Activity List to View Discrepant Forms

Note: Skip this Exercise if the Activity List was not explained in the tutorial.

Scenario: You have completed Data Entry for the patient identified in training case #2. Now you want to view only those CRFs that contain active discrepancies.

Note: Skip this Exercise if the Activity List was not explained in the tutorial. Be sure to switch back to the Activity List display for this Exercise.

Step	Instructions/Screen Visual	Notes
	Open the Activity List	
	Select the site identified for your training cases	
	Select the patient inserted for training case #2	
	Select View _____ discrepancies for Patient _____.	
	How many forms are displayed on the RDC spreadsheet?	
	Which eCRFs are displayed?	
	What color are the icons representing those eCRFs?	

Print a Patient Case Report Form

Scenario: *You have been tasked with printing all verified CRFs for Training Case 1.*

STEP	Instructions/Screen Visual	Notes
	Using the eCRFs created from the Sample CRFs found in Training Case 1 provided to you by your instructor, perform the following tasks:	
	Print all verified CRFs.	
	Which CRFs from the study database printed?	

Print a Blank Case Report Form

Scenario: *You have been tasked with printing a complete set of Blank CRFs for this study.*

STEP	Instructions/Screen Visual	Notes
	Print a complete set of Blank CRFs.	

RDC 4.5 <u>Classic</u> Setup Instructions

Download and Installation Instructions for:

- *JInitiator 1.1.8.21*
- *RDC 4.5 Classic Test Connection Instructions*

Second Edition
September 20, 2005

This edition of this manual supersedes any previous edition.

Table of Contents

Installing JInitiator 1.1.8.21

1. Type https://www9.wesrdc.com/opa45/RDCLaunch.htm in the Address box and hit Enter.
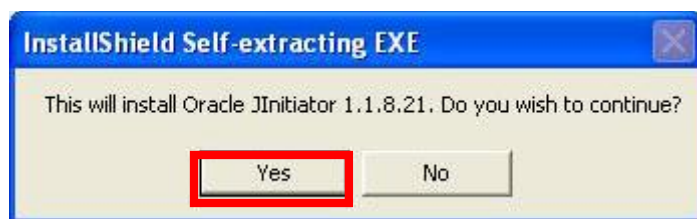
2. Click on **Login** button.
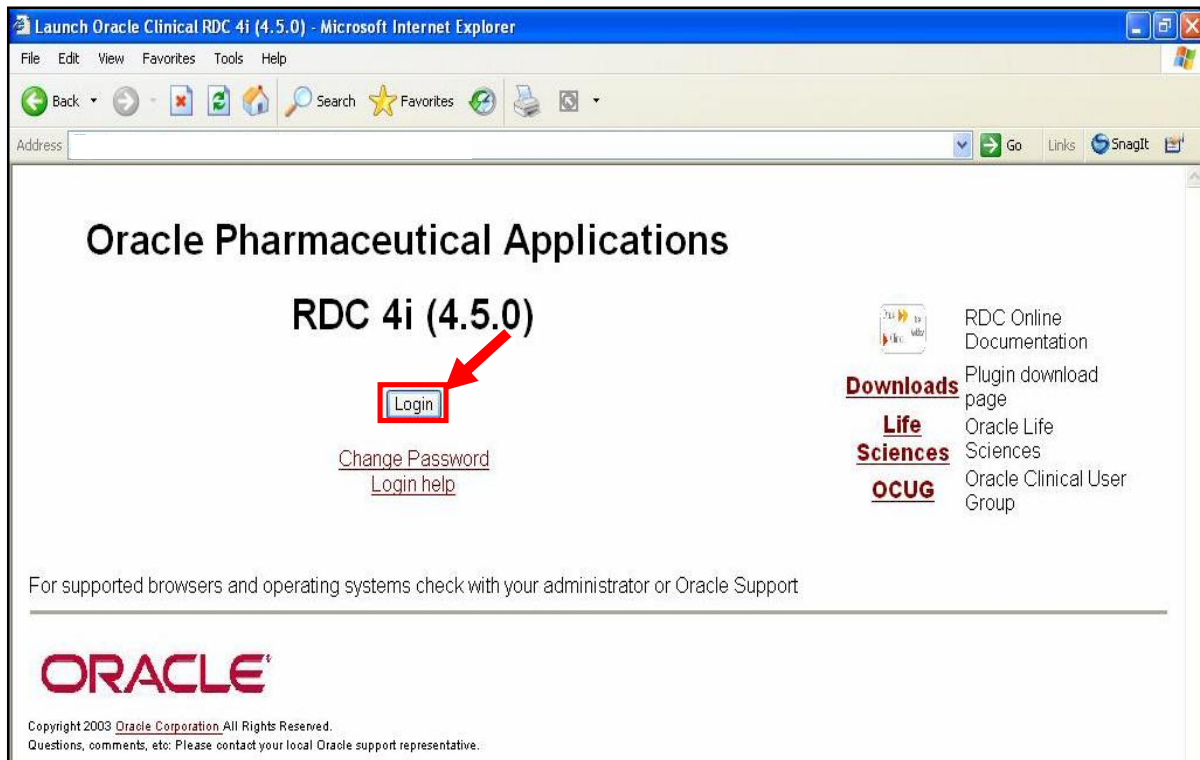
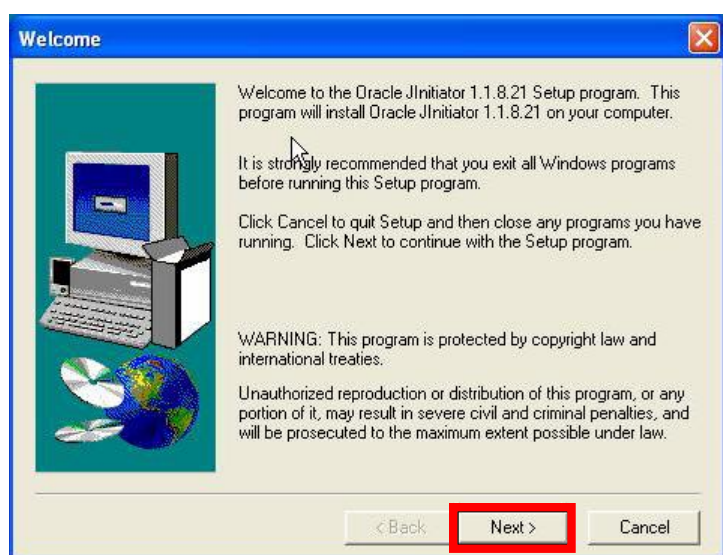3. The RDC Run Time dialog box appears briefly.
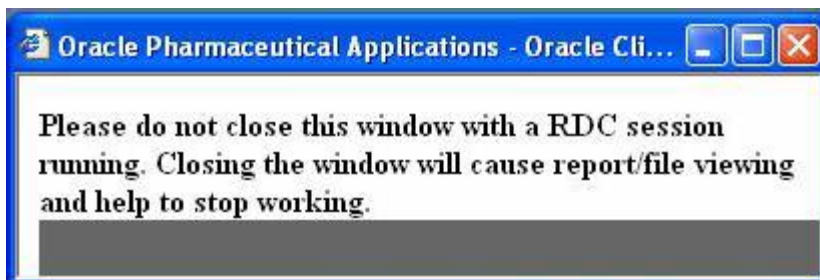
Installing JInitiator 1.1.8.21

4. Click on the **Yes** button.

5. The JInitiator installation set-up program will launch. Click the **Next** button to begin the Installation.

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Page 2

Installing JInitiator 1.1.8.21

6. When prompted for the destination directory, accept the default location by clicking the **Next** > button.
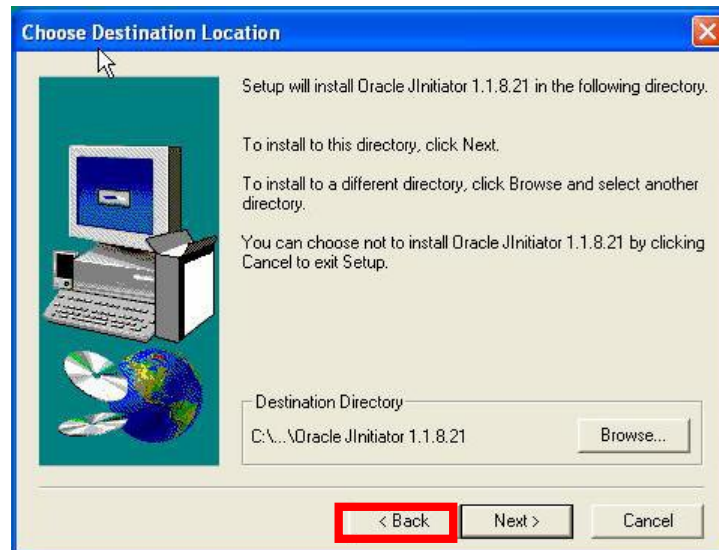
7. When the installation complete dialog box displays, click the OK button.
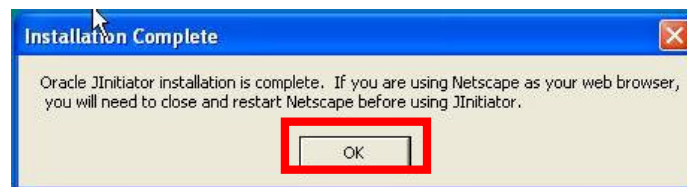
8. Close the open Internet browser.

9. Restart your Internet browser.

10. Re-enter URL for the Oracle Pharmaceutical Applications (see step 1).

Congratulations, you completed the Installation and Set-up of Jinitiator 1.1.8.21!

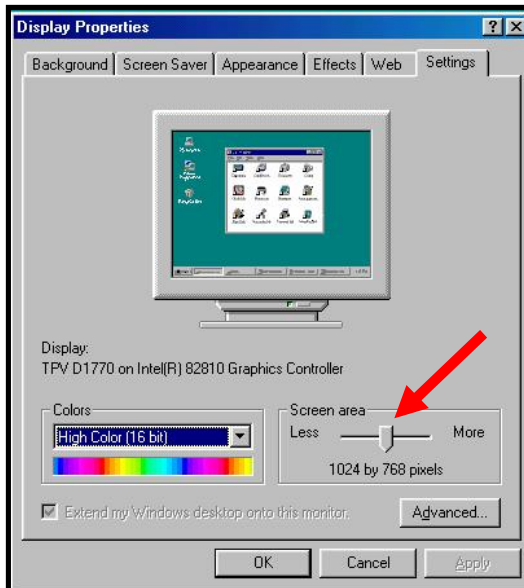# Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

Adjust the Screen Resolution to 1024 x 768

To adjust the screen resolution:

1. Click the **Start** button and select **Settings**, and then **Control Panel**

2. From the **Control Panel** select **Display** to open the **Display Properties** screen.

3. Click on the **Settings** tab
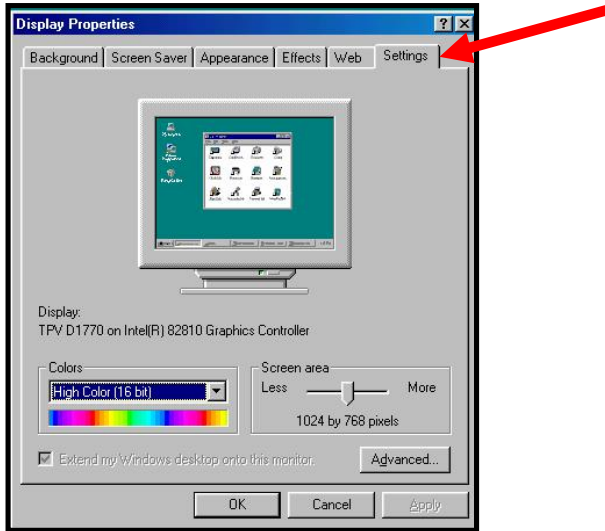
4. In the **Screen area** section of the dialog box, click and hold your left mouse button as you move the pointer to 1024x768 pixels. (Windows default setting is either 800 by 600 pixels or 640 by 480 pixels)

Adjust the Screen Resolution to 1024 x 768

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

5. Click **Apply**, and then click **OK**.

6. Depending on your system, you may need to restart your computer for the settings to take effect.

Install Version 6.0 or higher of Microsoft Internet Explorer

In order to use RDC 4.5 Classic, you must have Microsoft Internet Explorer 6.0 or higher installed on your PC.

To determine which version of Microsoft Internet Explorer you are currently running, please following these steps:
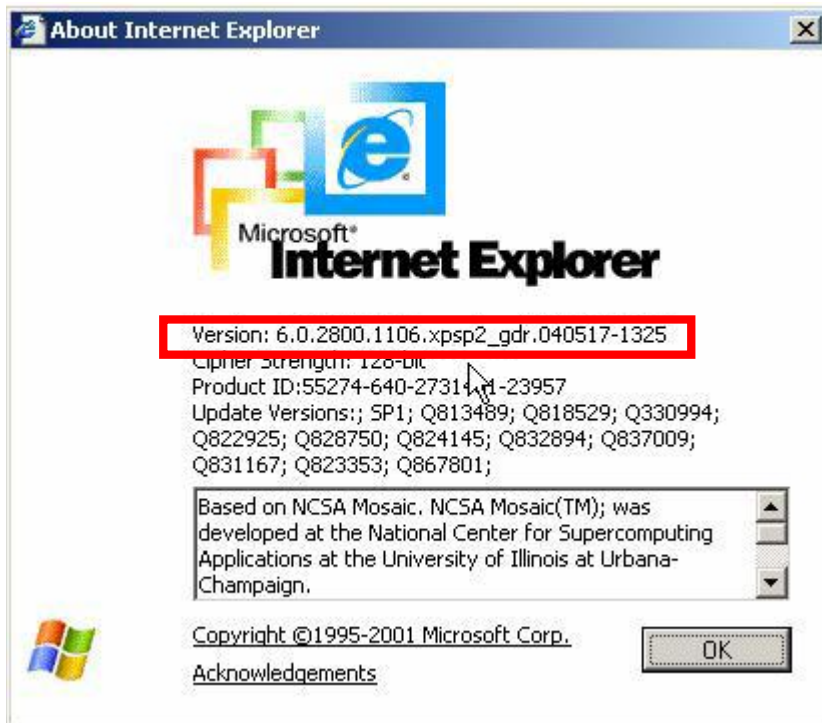
1. Open Microsoft Internet Explorer

2. Click Help => About Internet Explorer

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

Install Version 6.0 or higher of Microsoft Internet Explorer

3. The version number will be displayed on the About Internet Explorer screen.

4. If you do not have Microsoft Internet Explorer 6 or higher installed on your PC, please check with your local information technology (IT) person to assist you with the download and installation of a compatible version.

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Page 6

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

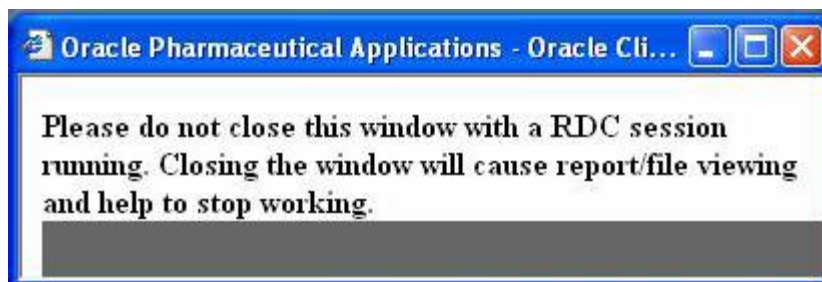*Before proceeding with the following steps, close any programs you have running.*

1. Open web browser (MS Internet Explorer.)

Type https://www5.wesrdc.com/opa45/RDCLaunch.htm in the Address box and hit Enter.

2. Click on **Login** button.
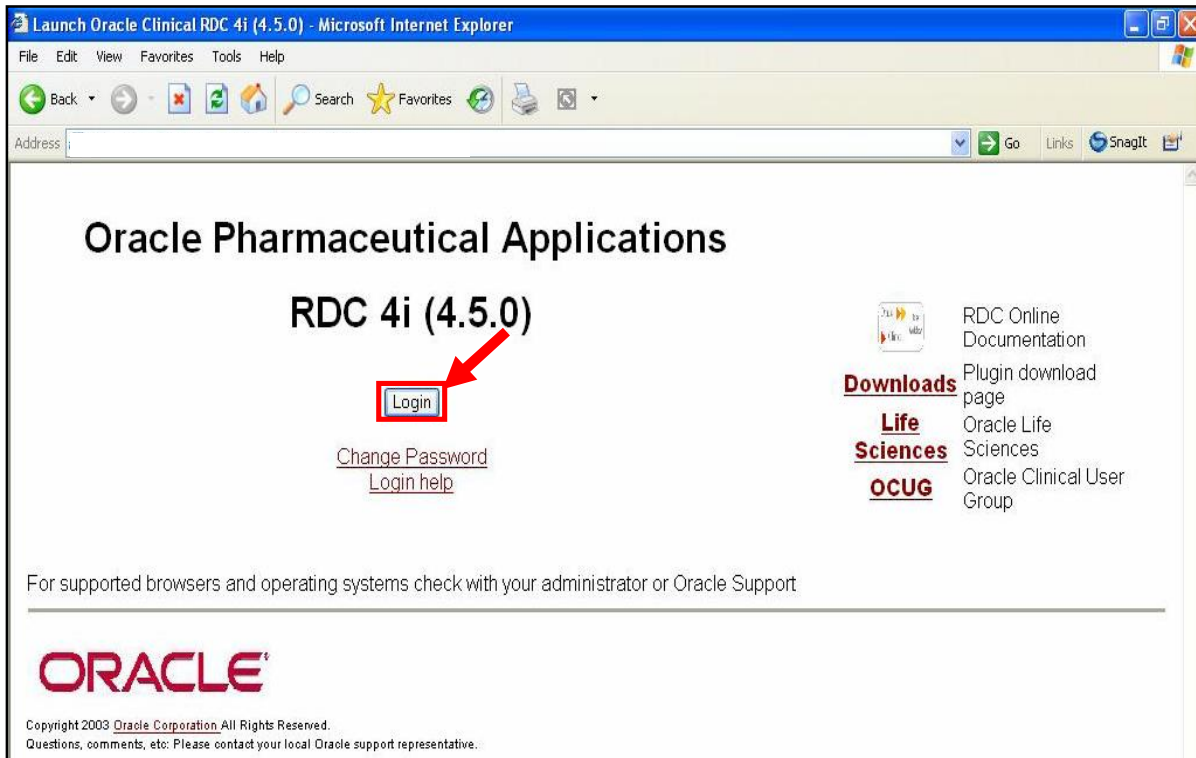
3. The RDC Run Time dialog box appears briefly.

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

4. At the database logon screen, enter the information provided in the email sent to you (use the Tab key to move from one field to the next.)

    NOTE: For security reasons, do not print the email containing your test username and password. Do not write the information down. Maintaining computer security for all Westat networks is everyone's responsibility.

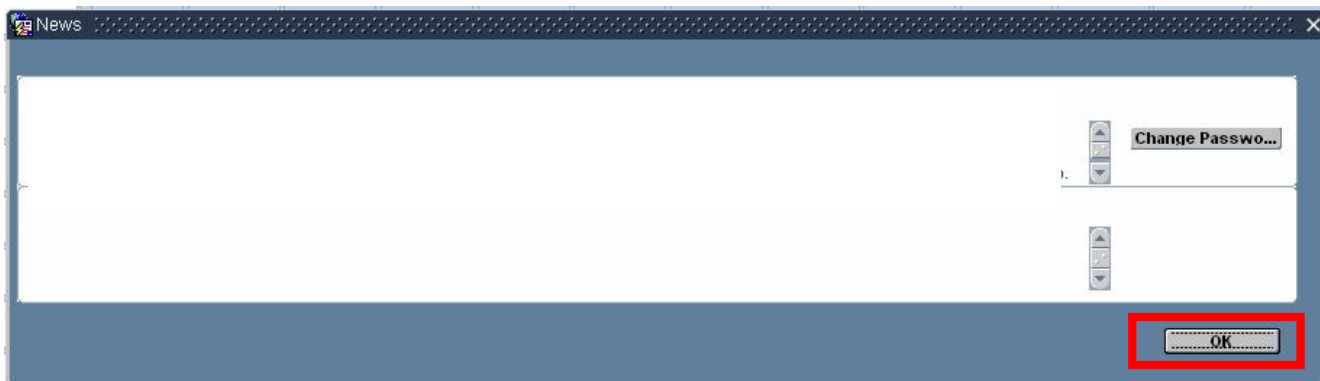   If you are having trouble with the test connection login process, contact

- DCP RDC users: 1-888-662-8354 or nci-dcpmonitoring@westat.com
- CTSU RDC users: 1-888-823-5923 or CTSUContact@westat.com
- ATN RDC users: atnrdc@westat.com
- Other RDC users: 1-800-509-5559 or HelpCenter@westat.com

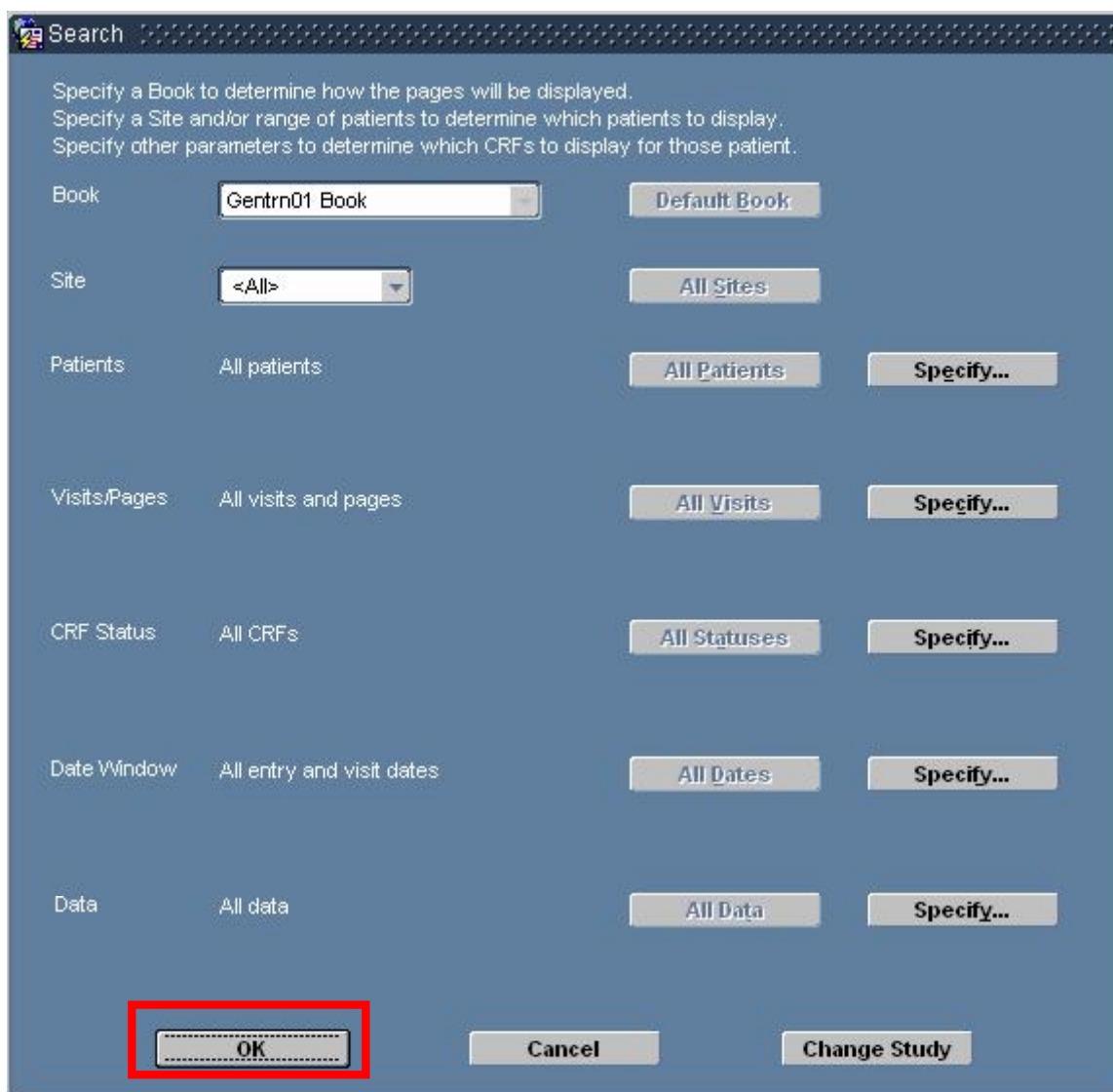5. When you entered the required login information, click the Connect button.

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Page 8

6. Click on the OK button.

7. Click on the OK button.

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Page 9

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

8. Click on the form icon to display the eCRF.

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

9. The eCRF will be displayed.

10. Click on the Close button on the eCRF to exit.

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Page 11

Testing Your Connection to Remote Data Capture (RDC) 4.5 Classic

11. To exit the application, click on <u>File</u> and select <u>Exit</u> from the drop down menu.
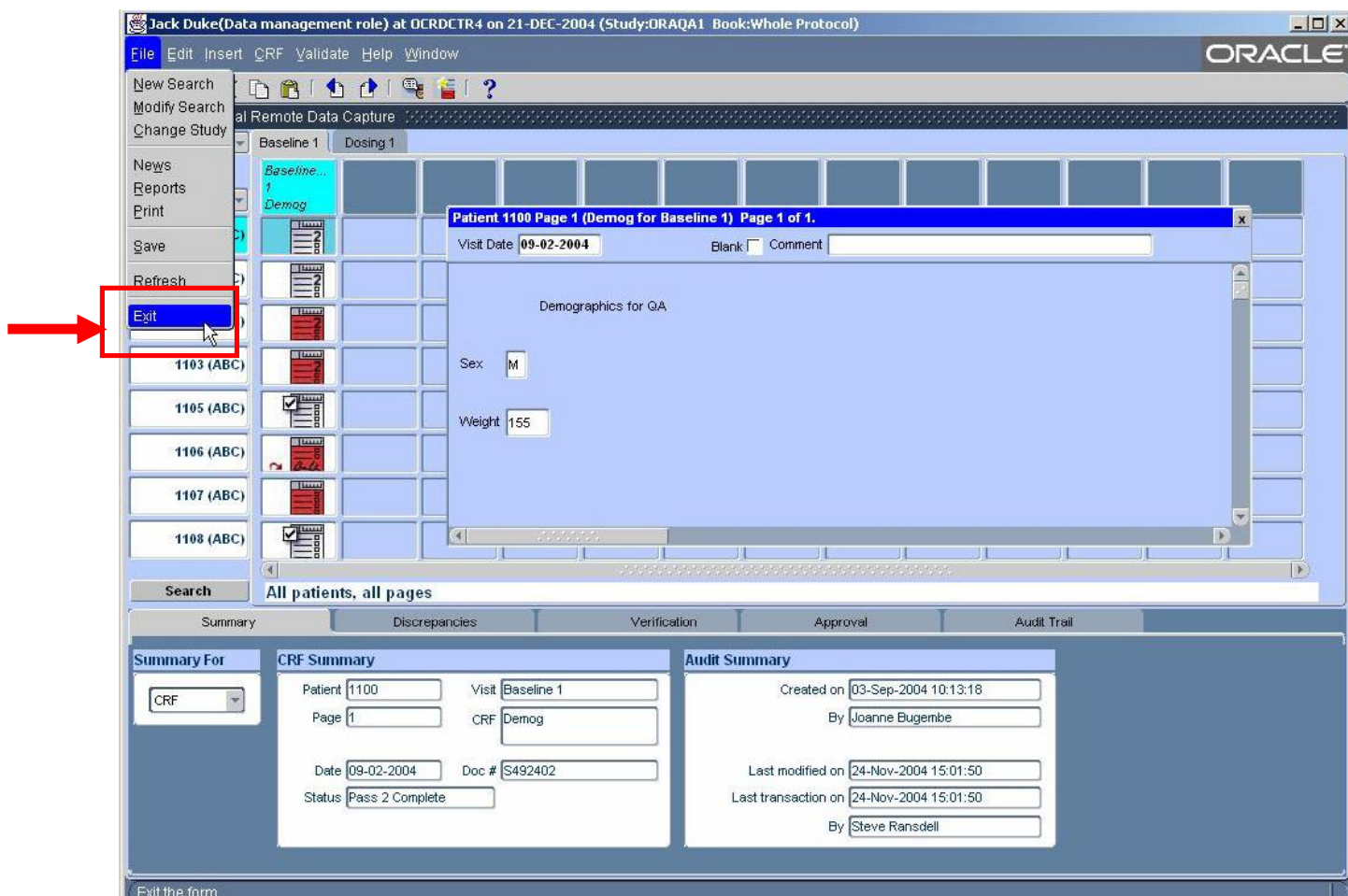
12. Click on the X in the dialog box to close the "Oracle Pharmaceutical…." Window
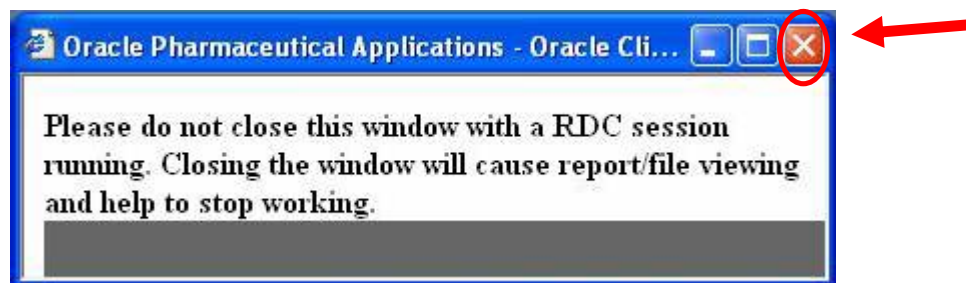
13. Click on the X in the dialog box to close the web browser.

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Page 13